

2026 Rheumatology Updates for the Internist and Primary Care



Amish J. Dave, MD, MPH
Virginia Mason Medical Center
Virginia Mason Franciscan Health

Disclosures

- Board-certified rheumatologist at Virginia Mason Medical Center and Director of CME at Virginia Mason Medical Center
- Associate program director, rheumatology fellowship, Virginia Mason Medical Center
- Board member of the American Board of Internal Medicine (ABIM) Rheumatology
- Great West Board of the Arthritis Foundation
- Board of Trustees of Coalition of State Rheumatology Organizations
- Washington Rheumatology Alliance Board
- AMA Delegate for Washington state
- Former president, Northwest Rheumatism Symposium

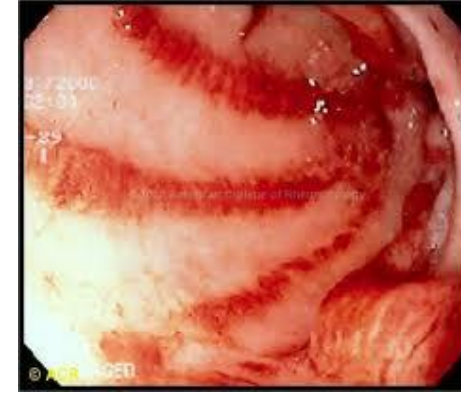
No pharmaceutical company affiliations or support

Topics

1. Systemic Sclerosis
2. Psoriatic arthritis and spondyloarthropathy
3. Vasculitis
4. Rheumatoid arthritis
5. SLE
6. Gout
7. Potpourri



Systemic Sclerosis



- Systemic sclerosis (SSc) is an autoimmune disease involving a triad of autoantibody production, fibroblast dysfunction, and endothelial cell dysfunction
- Classification into limited and diffuse systemic sclerosis forms with limited disease more often associated with pulmonary artery hypertension and diffuse form more associated with interstitial lung disease
- The disease process can involve protean manifestations with hallmarks including Raynaud's, positive ANA serology, calcinosis, skin tightening (scleroderma), sclerodactyly, esophageal dysfunction, difficulty swallowing, tendon friction rubs, lung disease, cardiac disease, small intestinal bacterial overgrowth, telangiectasias, and more!



2013 Classification Criteria for Research Studies

Table 1 The American College of Rheumatology/European League Against Rheumatism criteria for the classification of systemic sclerosis*

Item	Sub-item(s)	Weight/ score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints (<i>sufficient criterion</i>)	—	9
Skin thickening of the fingers (<i>only count the higher score</i>)	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions (<i>only count the higher score</i>)	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	—	2
Abnormal nailfold capillaries	—	2
Pulmonary arterial hypertension and/or interstitial lung disease (<i>maximum score is 2</i>)	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	—	3
SSc-related autoantibodies (anticentromere, anti-topoisomerase I [anti-Scl-70], anti-RNA polymerase III) (<i>maximum score is 3</i>)	Anticentromere	3
	Anti-topoisomerase I	
	Anti-RNA polymerase III	

*These criteria are applicable to any patient considered for inclusion in a systemic sclerosis study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (eg, nephrogenic sclerosing fibrosis, generalised morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).

†The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥ 9 are classified as having definite systemic sclerosis.

SSc, systemic sclerosis.

► Rheumatology (Oxford). 2025 Jul 17;64(12):6023–6035. doi: [10.1093/rheumatology/keaf392](https://doi.org/10.1093/rheumatology/keaf392)

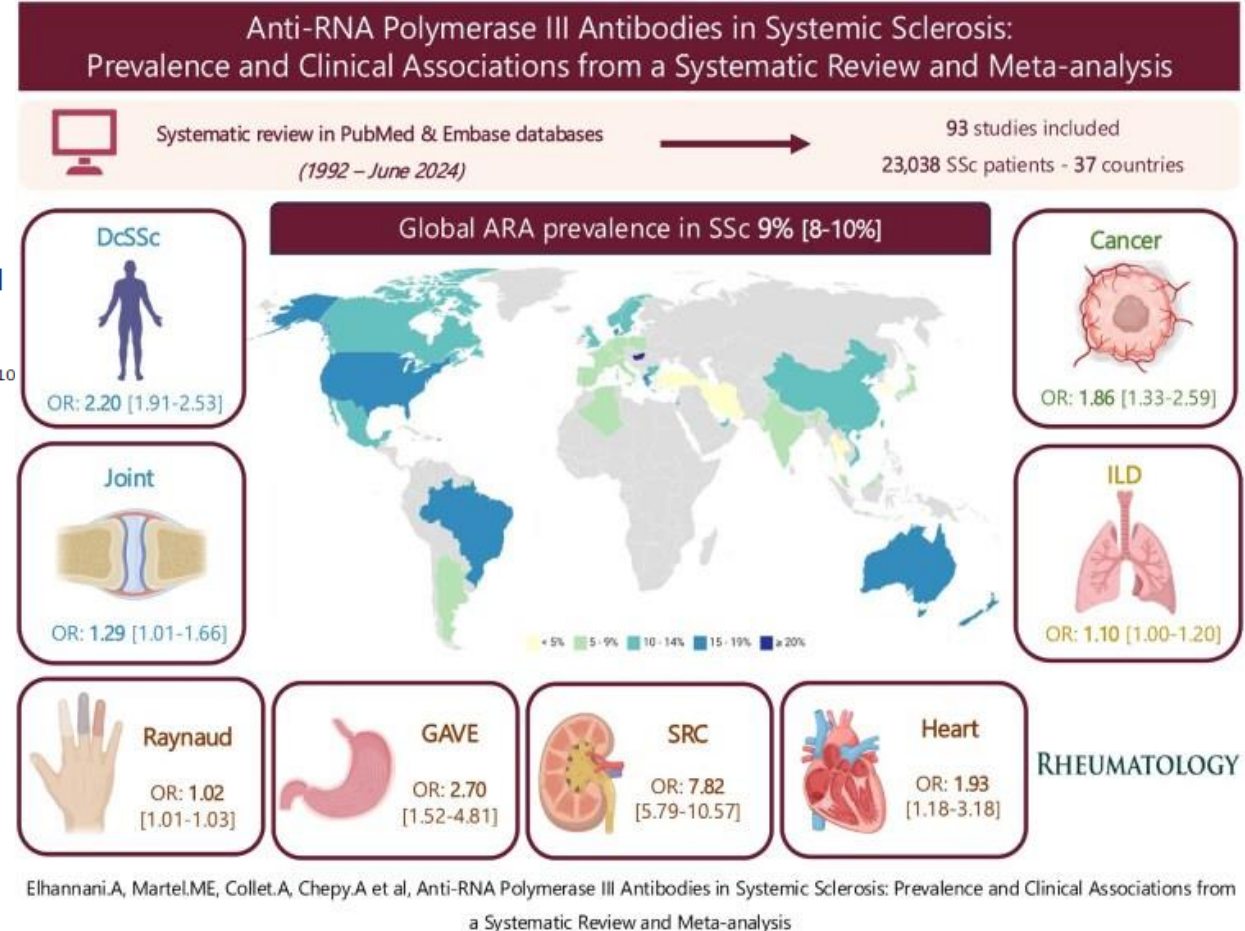
Anti-RNA polymerase III antibodies in systemic sclerosis: prevalence and clinical associations from a systematic review and meta-analysis

Abderrahmane Elhannani^{1,2,#}, Marie-Elise Martel^{3,4,#}, Aurore Collet^{5,6}, Aurélien Chepy^{7,8}, Sébastien Sanges^{9,10},
Éric Hachulla^{11,12}, Sylvain Dubucquoi^{13,14}, David Launay^{15,16}, Vincent Sobanski^{17,18,19,✉}

► Author information ► Article notes ► Copyright and License information

PMCID: PMC12671874 PMID: [40676730](https://pubmed.ncbi.nlm.nih.gov/40676730/)

- Anti-ribonucleic acid (RNA) polymerase III antibodies are found in many patients with systemic sclerosis, but it was previously unclear what specific clinical features these antibodies were associated with
- A meta-analysis of 93 studies with 23,038 patients found that RNA polymerase III antibodies were found in 9% of patients
- These patients were more likely to have diffuse cutaneous disease, scleroderma renal crisis, gastric antral vascular ectasia (GAVE), cardiac involvement, interstitial lung disease, and cancer



Key point: patients who are positive for RNA polymerase III warrant more aggressive monitoring for severe organ-system complications

Oesophageal dysmotility patterns are associated with distinct clinical phenotypes and prognosis in patients with systemic sclerosis

Luis G Alcala-Gonzalez¹, Alfredo Guillen-Del-Castillo², Ariadna Aguilar^{1 3}, Claudia Barber^{1 3}, Carolina Malagelada^{1 3 4}, Laura Polo Figueras¹, Laura Triginer², Claudia Codina-Clavaguera², Michael Hughes^{5 6}, Jordi Serra^{1 3}, Carmen P Simeón-Aznar², Zsuzsanna H McMahan⁷

Affiliations + expand

PMID: 40795829 PMID: PMC12671867 (available on 2026-08-09)

DOI: [10.1093/rheumatology/keaf433](https://doi.org/10.1093/rheumatology/keaf433)

- While esophageal dysmotility is common in systemic sclerosis, whether manometric patterns identify distinct clinical phenotypes is unclear
- 201 patients with SSc were followed for 400+ person-years
- High-resolution manometry showed absent contractility in 43%, ineffective motility in 28%, and normal motility in remaining patients
- Patients with absent contractility on manometry were at higher risk of diffuse SSc, more severe digital ulcers, gastric vascular ectasia, higher risk of lung transplant, and higher risk of death even with adjusting for ILD presence
- Patients with ineffective motility were more likely to have limited SSc
- Key Point: Manometry might help clinicians identify higher risk SSc patients

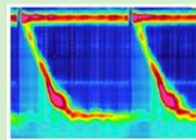
Esophageal dysmotility patterns are associated with distinct clinical phenotypes and prognosis in patients with systemic sclerosis

OBJECTIVE:

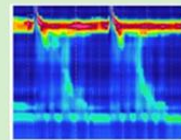
We aimed to determine whether esophageal dysmotility patterns, by high-resolution esophageal manometry, were associated with distinct clinical phenotypes and different outcomes.

METHODS:

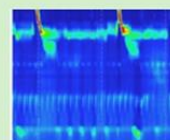
Retrospective cohort study of 201 consecutive patients with systemic sclerosis who underwent high-resolution esophageal manometry.



Normal motility
(n=58)



Ineffective
esophageal
motility (n=57)



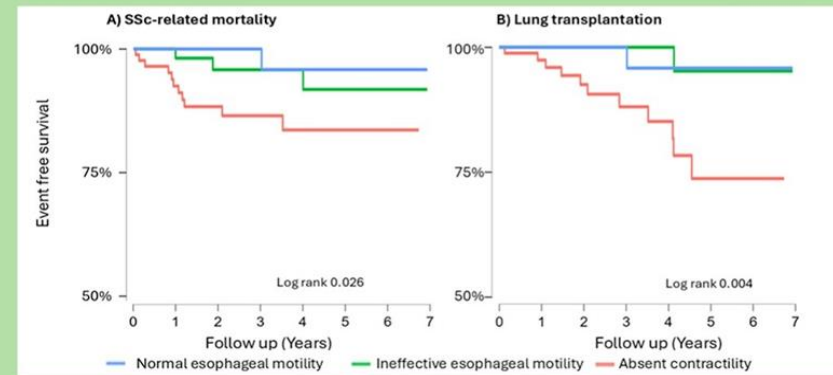
Absent
contractility
(n=86)

Methods

RESULTS:

Absent contractility presents with a vascular phenotype (Gastric vascular ectasia, more digital ulcers and microvascular abnormalities on capillaroscopy) and **ineffective esophageal motility** seems to be a distinct motility disorder, linked to anti-centromere positivity.

Absent contractility is associated with worse clinical outcomes during follow-up.



Key findings

RHEUMATOLOGY

Alcala-Gonzalez et al. Esophageal dysmotility patterns are associated with distinct clinical phenotypes and prognosis in patients with systemic sclerosis. *Rheumatology*.

Identification of Risk Factors for Incident Left Ventricular Systolic Dysfunction and Predictors of Cardiac Recovery in Patients With Systemic Sclerosis

Ji Soo Kim [✉](#), Rachel S. Wallwork, Carrie L. Richardson, Adrienne Woods, Monica Mukherjee, Steven Hsu, Julie J. Paik, Christopher A. Mecoli, Laura K. Hummers, Fredrick M. Wigley, Scott L. Zeger, Ami A. Shah [✉](#)

First published: 13 October 2025 | <https://doi.org/10.1002/art.43408> | [VIEW METRICS](#)

- Cardiac disease is a leading cause of death in SSc with most patients having clinical or subclinical disease
- Clinical predictors of left ventricular systolic dysfunction were identified in a registry of >2300 patients with >13,000 echocardiograms
- LV systolic dysfunction <50% was predicted by male sex, black race, presence of pulmonary hypertension, kidney disease, higher skin score, atrial fibrillation, and diffuse skin disease
- Severe LV systolic dysfunction $\leq 35\%$ was predicted by male sex, black race, presence of pulmonary hypertension, kidney disease, higher skin score plus anti-Ku antibodies and skeletal myopathy

Key Point: We are getting better at identifying risk factors for heart failure and cardiac disease in systemic sclerosis

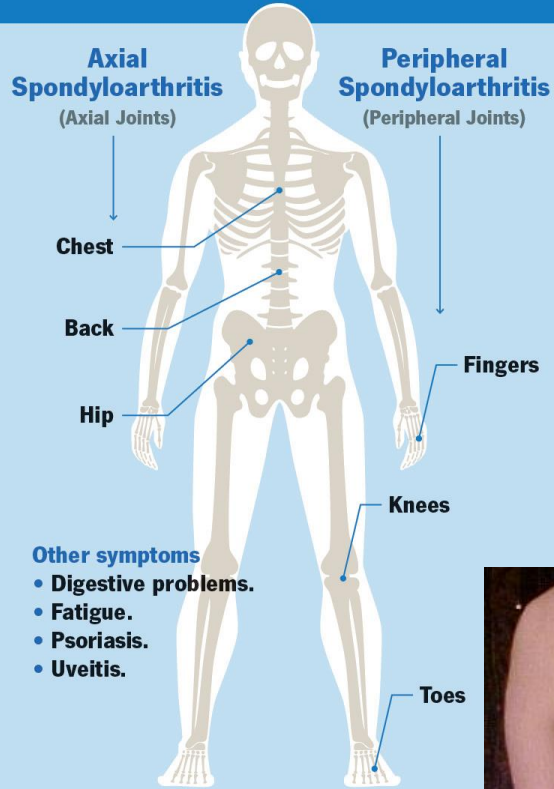


Table 4. Multiple logistic regression analyses examining factors that are associated with cardiac recovery*

Variable	EF < 50% to EF $\geq$ 50%		EF $\leq$ 35% to EF > 35%	
	Adjusted OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Age at onset, y	1.01 (0.99, 1.02)	0.445	1.01 (0.99, 1.04)	0.305
Disease duration, y	0.99 (0.97, 1.02)	0.561	0.98 (0.95, 1.02)	0.299
DLco < 60	1.22 (0.84, 1.78)	0.285	1.39 (0.74, 2.61)	0.303
mRSS	1.01 (0.99, 1.03)	0.349	0.98 (0.96, 1.01)	0.248
Anti-RNA polymerase III	1.76 (1.10, 2.80)	0.018	1.71 (0.75, 3.89)	0.202
Moderate–severe kidney disease	1.48 (0.96, 2.29)	0.076	1.96 (0.96, 4.01)	0.066
Anti-Ro52	0.83 (0.55, 1.25)	0.368	1.32 (0.67, 2.59)	0.424
Diffuse	0.70 (0.45, 1.09)	0.117	–	–
Tendon friction rubs	0.38 (0.22, 0.66)	0.001	–	–
RVSP $\geq$ 45	0.76 (0.52, 1.10)	0.144	–	–
ILD	–	–	1.14 (0.59, 2.21)	0.691
Diabetes mellitus	–	–	0.18 (0.04, 0.83)	0.028
Raynaud phenomenon	–	–	1.32 (0.71, 2.25)	0.420

Spondyloarthropathy

Types of Spondyloarthritis Affected areas of the body



Cleveland Clinic

- Spectrum of diseases including psoriatic arthritis, ankylosing spondylitis, IBD with IBD-associated spondyloarthropathies, hidradenitis suppurativa, anterior uveitis, enthesitis with or without positive HLA-B27
- Patients tend to have formation of new bone along with destruction of bone over time noted on imaging



X-ray – Similarities and differences between ankylosing spondylitis and psoriatic arthritis in the spine

New bone formation can be observed in both conditions, however, “atypical” **syndesmophytes** (bulky, non-marginal) are more common in PsA



Y-GRAPPIAns

Courtesy Denis Poddubnyy

GRAPPA

X-Rays – Destruction and new bone formation in PsA



Hands x-ray of a PsA patient with **destruction and new bone formation** at interphalangeal joints



Y-GRAPPIAns

Courtesy of Cristina Macia-Vila

GRAPPA

Table 3 FDA-approved therapies for PsA or RA

Class	Available agent	Indication	
		PsA	RA
Conventional synthetic DMARDs			
	Methotrexate	*	✓
	Leflunomide	—	✓
	Corticosteroids	✓†	✓
	Hydroxychloroquine	—	✓
	Sulfasalazine	*	✓
	Ciclosporin	*	✓‡
Biological DMARDs			
TNF-α inhibitors	Etanercept	✓	✓
	Infliximab	✓	✓
	Adalimumab	✓	✓
	Golimumab	✓	✓
	Certolizumab pegol	✓	✓
IL-17A inhibitor	Secukinumab	✓	—
	Ixekizumab	✓	—
IL-12/23 inhibitor	Ustekinumab	✓	—
IL-6 receptor inhibitors	Tocilizumab	—	✓
	Sarilumab	—	✓
IL-1 receptor antagonist	Anakinra	—	✓
T-cell activation inhibitor	Abatacept	✓	✓
CD20 inhibitor	Rituximab	—	✓
Targeted synthetic oral small-molecule DMARDs			
PDE4 inhibitor	Apremilast	✓	—
Janus kinase inhibitor	Tofacitinib	✓	✓

*Commonly used off-label.
†Discontinuation of systemic corticosteroids can cause serious psoriasis flare and dosing should be tapered instead of abruptly stopped.
‡Ciclosporin is not commonly used in RA.
CD, cluster of differentiation; DMARD, disease-modifying antirheumatic drug; FDA, Food and Drug Administration; IL, interleukin; PDE4, phosphodiesterase 4; PsA, psoriatic arthritis; RA, rheumatoid arthritis; TNF, tumour necrosis factor.

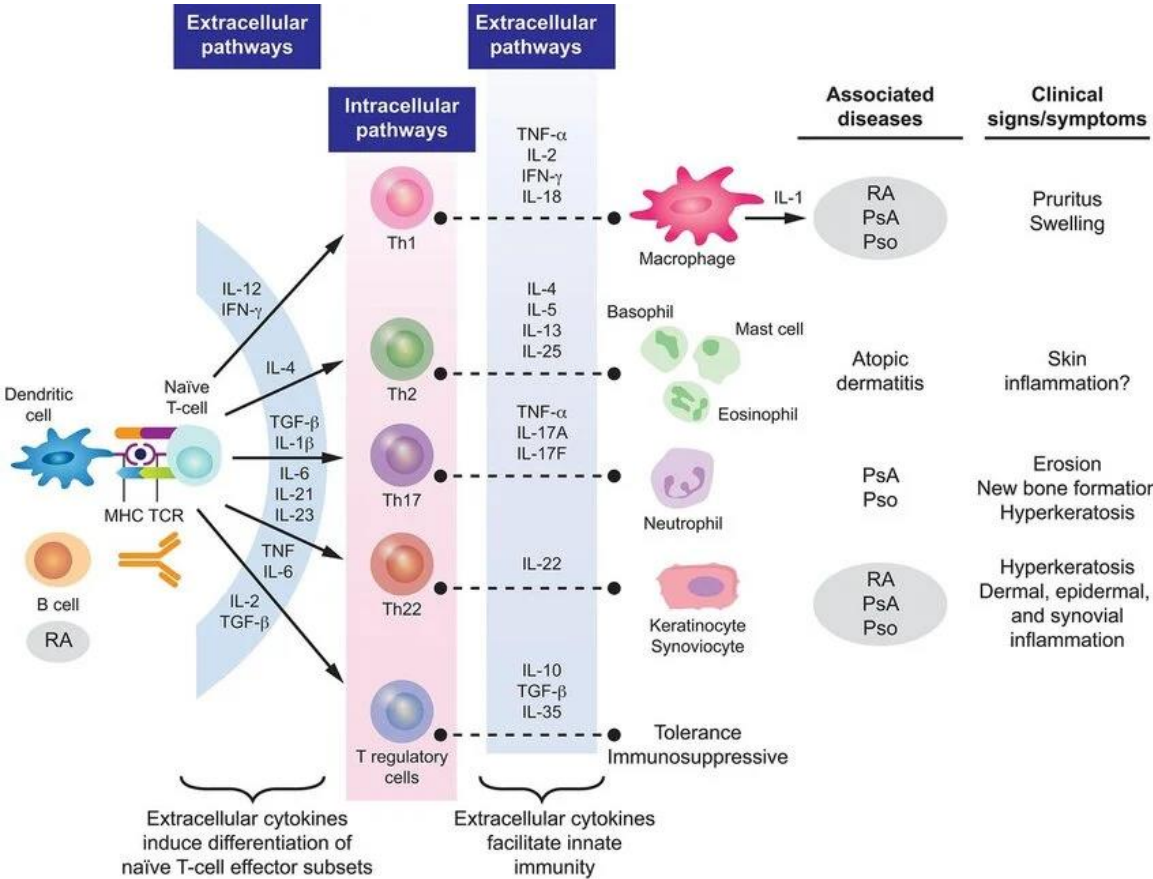
RMD Open

Rheumatic & Musculoskeletal Diseases

REVIEW

Distinguishing rheumatoid arthritis from psoriatic arthritis

Joseph F Merola,¹ Luis R Espinoza,² Roy Fleischmann³



REVIEW

Deucravacitinib for the treatment of psoriatic arthritis: the evidence so far

Ana Martins^{1,2}, Ana Maria Lê³, Tiago Torres^{3,4}

¹Department of Rheumatology, Centro Hospitalar Universitário de São João, Porto, Portugal; ²Department of Medicine, Faculdade de Medicina da Universidade do Porto, Porto, Portugal; ³Department of Dermatology, Centro Hospitalar Uni- versitário do Porto, Porto, Portugal; ⁴Instituto de Ciências Biomédicas Abel Salazar, University of Porto, Porto, Portugal

- April 2026 – Deucravacitinib (an oral tyrosine kinase 2 inhibitor) is the newest DMARD approved for adults with psoriatic arthritis per the US FDA
- The drug already had approval for plaque psoriasis with four-year safety data published in 2025
- Two trials of >1000 patients with peripheral psoriatic arthritis showed that, at week 16, patients treated with 6 mg deucravacitinib daily had statistically significant improvement in disease activity compared to placebo (54% vs 34%), as well as improvements in patient-reported outcomes for physical function, pain, and general health
- More research needed on efficacy for axial psoriatic arthritis

Table 1. Secondary and additional efficacy endpoints at week 16.

	Placebo (n=66)	Deucravacitinib	
		6 mg daily (n=70)	12 mg daily (n=67)
Primary endpoint			
ACR-20 Response rate, % (95% CI); <i>p</i> value	31.8 (20.6 to 43.1)	52.9 (41.2 to 64.6); 0.0134	62.7 (51.1 to 74.3); 0.0004
Secondary endpoints			
HAQ-DI Adjusted mean change from baseline (95% CI); <i>p</i> value	-0.1 (-0.2 to 0.0)	-0.4 (-0.5 to -0.2); 0.0020	-0.4 (-0.5 to -0.3); 0.0008
SF36-PCS Adjusted mean change from baseline (95% CI); <i>p</i> value	2.3 (0.4 to 4.2)	5.6 (3.8 to 7.5); 0.0062	5.8 (3.9 to 7.7); 0.0042
Additional endpoints			
ACR-50 Response rate, % (95% CI); <i>p</i> value	10.6 (3.2 to 18.0)	24.3 (14.2 to 34.3); 0.0326	32.8 (21.6 to 44.1); 0.0016
ACR-70 Response rate, % (95% CI); <i>p</i> value	1.5 (0.0 to 4.5)	14.3 (6.1 to 22.5); 0.0044	19.4 (9.9 to 28.9); 0.0003
Enthesis resolution (LEI) Response rate, % (95% CI); <i>p</i> value	<i>n</i> =31 22.6 (7.9 to 37.3)	<i>n</i> =39 51.3 (35.6 to 67.0); 0.0138	<i>n</i> =26 50.0 (30.8 to 69.2); 0.0393
Dactylitis resolution Response rate, % (95% CI); <i>p</i> value	<i>n</i> =25 60.0 (40.8 to 79.2)	<i>n</i> =30 76.7 (61.5 to 91.8); NA	<i>n</i> =24 79.2 (62.9 to 95.4); NA
PASDAS Adjusted mean change from baseline (95% CI); <i>p</i> value	-1.1 (-1.5 to -0.7)	-2.0 (-2.4 to -1.6); 0.0003	-2.1 (-2.5 to -1.8); <0.0001
DAPSA Adjusted mean change from baseline (95% CI); <i>p</i> value	-13.3 (-17.7 to -9.0)	-23.2 (-27.5 to -19.0); 0.0004	-25.6 (-30.0 to -21.2); <0.0001
MDA Response rate, % (95% CI); <i>p</i> value	7.6 (1.2 to 14.0)	22.9 (13.0 to 32.7); 0.0119	23.9 (13.7 to 34.1); 0.0068

ACR, American College of Rheumatology; DAPSA, Disease Activity Index for Psoriatic Arthritis; HAQ-DI, Health Assessment Questionnaire – Disability Index; LEI, Leeds Enthesitis Index; MDA, Minimal Disease Activity; NA, not available; PASDAS, Psoriatic Arthritis Disease Activity Score; SF36-PCS, Short Form-36-Physical Component Summary.
Adapted from ref.²⁹

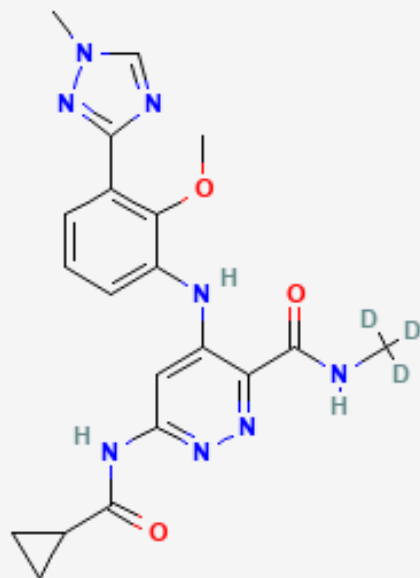
Deucravacitinib in plaque psoriasis: Four-year safety and efficacy results from the Phase 3 POETYK PSO-1, PSO-2 and long-term extension trials

[This article relates to:](#) [▼](#)

April W. Armstrong [✉](#) Mark Lebwohl, Richard B. Warren, Howard Sofen, Akimichi Morita, Carle Paul, Kim A. Papp, Matthew J. Colombo, Julie Scott, John Vaile, Joe Zhuo, Eleni Vritzali ... See all authors [▼](#)

First published: 06 March 2025 | <https://doi.org/10.1111/jdv.20553> | [VIEW METRICS](#)

Linked article: I. Birkenmaier et al. *J Eur Acad Dermatol Venereol* 2025;39:1220–1221. <https://doi.org/10.1111/jdv.20751>



Deucravacitinib in plaque psoriasis: 4-Year safety and efficacy

Deucravacitinib

- Oral, selective, allosteric TYK2 inhibitor
- Approved for adults with moderate to severe plaque psoriasis in multiple countries

Phase 3 POETYK PSO-1, PSO-2, and LTE trials

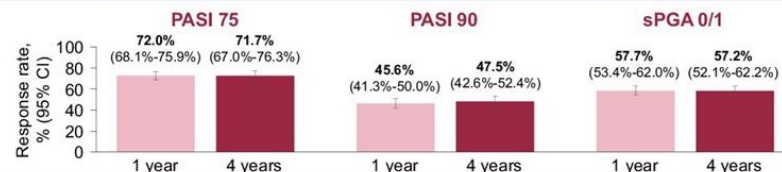
- Evaluated safety and efficacy of deucravacitinib in adults with moderate to severe plaque psoriasis through a cumulative 4 years (Week 208)
- Eligible patients enrolled in POETYK LTE after 1 year (52 weeks) in POETYK PSO-1 or PSO-2
- Received open-label deucravacitinib 6 mg once daily

1519 patients in the safety population (at least 1 dose of deucravacitinib)

COVID-19 pandemic coincided with cumulative Years 2 and 3



513 patients in the efficacy population (deucravacitinib from Day 1)



Patient-reported outcomes

Improvements in patient-reported outcomes maintained over 4 years

Deucravacitinib demonstrated a consistent long-term safety profile and maintained clinical efficacy and improvements in patient-reported outcomes through 4 years

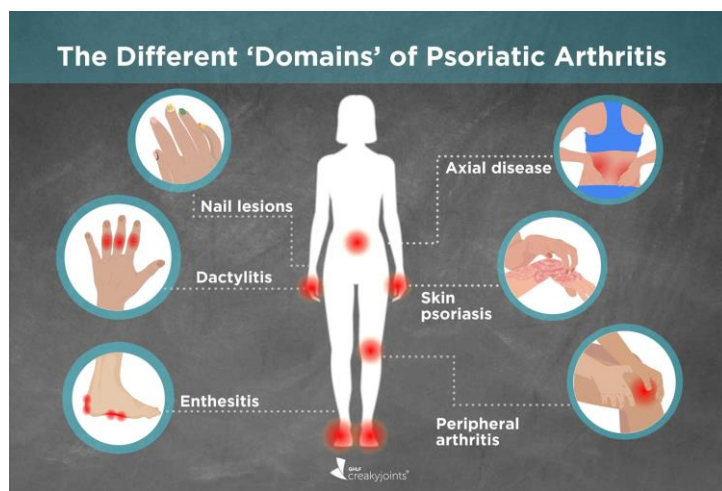
EAIR, exposure-adjusted incidence rate; LTE, long-term extension; PASI 75/90, ≥75%/≥90% reduction from baseline in Psoriasis Area and Severity Index; PY, person-years; sPGA 0/1, static Physician Global Assessment score of 0 (clear) or 1 (almost clear). Armstrong AW, Lebwohl M, Warren RB, Sofen H, Morita A, Paul C, et al. Deucravacitinib in plaque psoriasis: 4-year safety and efficacy results from the phase 3 POETYK PSO-1, PSO-2, and long-term extension trials. *J Eur Acad Dermatol Venereol*. 2024.

Psoriatic arthritis

Frequency and characteristics of axial involvement in psoriatic arthritis: results from the International Multicentre AXIS Study

Murat Torgutalp^{1,2,3,*}, Raquel Almodovar⁴, Valderilio F Azevedo⁵, Xenofon Baraliakos⁶, Filip Van den Bosch^{7,8}, Jürgen Braun^{6,9}, Vinod Chandran^{10,11,12,13}, Laura C Coates¹⁴, Atul Deodhar¹⁵, Torsten Diekhoff¹⁶, Filippo Fagni¹⁷, Alberto Floris¹⁸, Floris A van Gaalen¹⁹, Rodrigo Garcia-Salinas²⁰, Lianne S Gensler²¹, Niti Goel²², Alice B Gottlieb²³, Désirée van der Heijde¹⁹, Philip S Helliwell²⁴, Kay Geert A Hermann²⁵, Denis Poddubnyy^{1,10,11,13}

- The Axial Involvement in Psoriatic Arthritis (AXIS) cohort aimed at evaluating the frequency of and clinical and imaging features of axial involvement in psoriatic arthritis (PsA).
- In 409 patients with PsA in a prospective, multicenter study, 11.6% patients with axial spondyloarthritis had no back pain and 7.1% of patients had no sacroiliitis on MRI imaging
- 10% of patients initially diagnosed with axial spondyloarthritis had the diagnosis rescinded following review by radiologists
- Key Point: axial psoriatic arthritis diagnosis is subject to BOTH overdiagnosis and underdiagnosis. While patients might lack classic clinical and radiological features, imaging can be very helpful in ruling in or ruling out disease



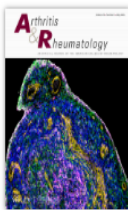
Inclusion criteria required participants to be:

- Adults (≥ 18 years) with a confirmed diagnosis of PsA by their treating rheumatologist.
- Meeting the CIASSification criteria for Psoriatic ARthritis [17].
- Having a musculoskeletal symptom duration of PsA ≤ 10 years.
- Treatment-naïve to biologic or targeted synthetic DMARDs.
- Able to understand and complete study questionnaires.

Data collection

We collected data using a standardised electronic case report form, which captured information in the following 3 main categories detailed in the study protocol [16]:

1. Clinical: demographic and disease (both psoriasis and PsA)-related characteristics were collected as described in the protocol [16] (Supplementary material Methods).
2. Laboratory: C-reactive protein (CRP), erythrocyte sedimentation rate, and HLA-B*27 status were assessed at the local laboratories of each centre. In addition, blood samples of participants were sent to the central laboratory at the University of Leeds for detailed genotyping.
3. Imaging: complete imaging of the axial skeleton that included both conventional radiographs and magnetic resonance imaging (MRI) of the SIJ and the spine according to a standard imaging protocol [16].



Early View

Online Version of Record
before inclusion in an issue

This article also appears in:
A&R Clinical Trials

Advertisement

Ixekizumab With Tirzepatide Achieved Greater Disease Control Than Ixekizumab Alone in Adults With Psoriatic Arthritis and Overweight or Obesity: Results From a Randomized Clinical Trial

Joseph F. Merola, Philip Mease, Alan Kivitz, Naveed Sattar, Laura C. Coates, Daniel Aletaha, Cynthia E. Kartman, Peter Fischer, Luna Sun, Pindaro Martinez-Osuna, Andris Kronbergs, Purvi Prajapati, Anabela Cardoso, Mark C. Genovese, [✉ Alexis Ogdie](#)

First published: 28 March 2026 | <https://doi.org/10.1002/art.70134> | [VIEW METRICS](#)

- In a 52-week trial of 271 patients with active PsA who were obese or overweight with ≥ 1 weight-related comorbidity, treatment with ixekizumab (IL-17 inhibitor) plus tirzepatide (a glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 dual agonist) led to higher remission rate than ixekizumab alone (34% vs 20%)
- Combination therapy also improved weight reduction, skin psoriasis, and patient-reported outcomes of fatigue and physical function

Background

Overweight and obesity affect 72–82% of people with active PsA and are associated with increased disease activity, attenuated response to biologics, and greater cardiometabolic burden.

Targeting both inflammation and weight may offer a more comprehensive treatment approach.

Study & Patient Population

Adults with active PsA and overweight with ≥ 1 weight-related comorbidity or obesity were enrolled, indicative of complex inflammatory-metabolic disease.

TOGETHER-PsA (NCT06588296) is a Phase 3b, open-label, randomized, 52-week trial.

Primary end point was simultaneous achievement of ACR50 response and $\geq 10\%$ weight reduction at Week 36.

Definitions & Abbreviations

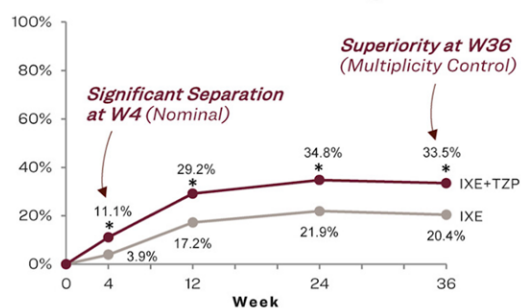
* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

ACR50 American College of Rheumatology 50 Responder Index; FACIT Functional Assessment of Chronic Illness Therapy; HAQ-DI Health Assessment Questionnaire-Disability Index; IXE ixekizumab; PRO patient-reported outcome; PsA psoriatic arthritis; TZP tirzepatide; W week

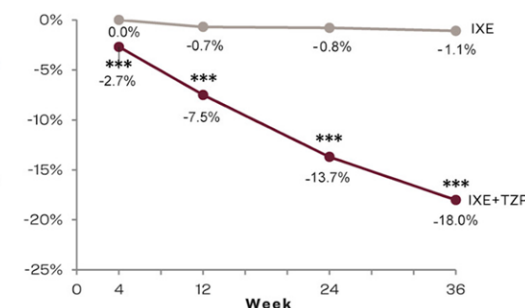
Ixekizumab With Tirzepatide Achieved Greater Disease Control Than Ixekizumab Alone in Adults With Psoriatic Arthritis and Overweight or Obesity: Results From a Randomized Clinical Trial

Results - Ixekizumab & Tirzepatide (N=138) vs Ixekizumab (N=133)

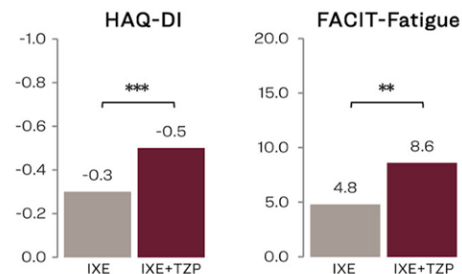
Percent of Patients Achieving ACR50



Percent Change in Body Weight



Improvement from Baseline in PROs at Week 36



Key Findings

- Primary outcome was achieved at Week 36 with IXE+TZP demonstrating superiority to IXE alone (31.7% vs 0.8%; $p < 0.001$).
- Improvements in ACR50 at 36 weeks, with improvement at 4 weeks before clinically meaningful weight loss.
- Improvements in PROs (including physical function and fatigue).
- Adverse events were consistent with each known drug profile.

Merola JF, Mease P, Kivitz A, et al. Ixekizumab with tirzepatide achieved greater disease control than ixekizumab alone in adults with psoriatic arthritis and overweight or obesity: results from a randomized clinical trial. Arthritis Rheumatol 2026.

Key Point: Weight loss plus immunosuppressive DMARD therapy might improve clinical outcomes in PsA

Effect of Nonsteroidal Anti-Inflammatory Drugs on Sacroiliac Joint Inflammation, as Seen on Magnetic Resonance Imaging, in Axial Spondyloarthritis

Gareth T. Jones,¹ Alexander N. Bennett,² Raj Sengupta,³ Pedro M. Machado,⁴ Helena Marzo-Ortega,⁵ Lorna Aucott,¹ Margaret A. Hall-Craggs,⁶ Timothy J. P. Bray,⁶ Alan Bainbridge,⁷ Ruairidh M. Gollifer,⁶ and Gary J. Macfarlane¹

- MRI is often used to detect evidence of active sacroiliitis in patients with axial spondyloarthropathy, but it is unclear what role NSAIDs have in masking inflammatory findings
- In a multicenter study of adults with axial spondyloarthropathy, 146 out of 286 patients had MRI evidence of active sacroiliitis after a 1-2 week NSAID washout
- In the 124 patients with active sacroiliitis who repeated an MRI once back on daily NSAIDs, 20% no longer had evidence of active sacroiliitis on MRI

Key Point: NSAID use can suppress MRI-detectable sacroiliac inflammation in some patients; do a brief NSAID washout before MRI imaging

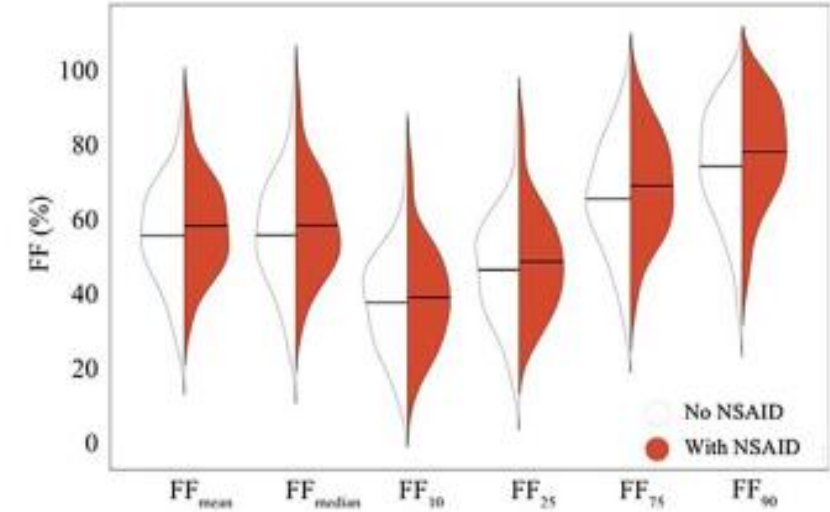


Figure 1. Violin plots demonstrating changes in quantitative magnetic resonance imaging parameters. FF-based histographic parameters are shown from before and after treatment. Note that the variability in the baseline FF values is effectively dealt with in the mixed-effect linear regression because each patient acts as their own control. FF, fat fraction; NSAID, nonsteroidal anti-inflammatory drug.

Prevalence and Predictors of Achieving Sustained Remission in Psoriatic Arthritis: A Swedish Nationwide Registry Study

Olafur Palsson, Jon T. Einarsson, Johan K. Wallman, Thorvardur J. Love, Bjorn Gudbjornsson and Meliha C. Kapetanovic

The Journal of Rheumatology October 2025, 52 (10) 997-1004; DOI: <https://doi.org/10.3899/jrheum.2024-1250>



- Despite access to insurance and modern DMARD therapies, many patients with PsA fail to achieve sustained remission
- In Sweden – a nation with a single-pay nationalized healthcare system – over 4669 patients with PsA who began biologic or targeted synthetic DMARD therapies were followed. Only 54% achieved sustained remission at some point

Key finding: Male sex and having fewer swollen joints were positive predictors of remission

Guselkumab: Pediatric First Approval

AdisInsight Report | Published: 16 February 2026

Volume 28, pages 217–224, (2026) [Cite this article](#)**Pediatric Drugs**[Aims and scope](#) →[Submit manuscript](#) →[Save article](#)

- Children can develop juvenile idiopathic arthritis
- In September 2025, the US FDA approved guselkumab (a human monoclonal antibody targeting IL-23) for children with psJIA ≥ 6 years of age
- The DMARD was approved based upon extrapolation from efficacy data in adult psoriatic arthritis as well as pharmacokinetic data in pediatric plaque psoriasis
- Guselkumab can be used as an alternative to TNF inhibitors in children with persistent peripheral arthritis despite treatment with methotrexate or sulfasalazine
- It can also be used as a third-line therapy for refractory axial arthritis

► Paediatr Drugs. 2025 Oct 28;28(1):69–81. doi: [10.1007/s40272-025-00725-2](https://doi.org/10.1007/s40272-025-00725-2)

Extrapolating Guselkumab Efficacy to Juvenile Psoriatic Arthritis from Adult Psoriatic Arthritis and Adult and Pediatric Psoriasis Data

Herta Crauwels^{1,‡}, Sarah Ringold^{2,‡}, Samantha Howard³, Bart Van Hartingsveldt⁴, Valerie Smith², Meg Jett², Tristan Baguet¹, Elizabeth Adamson⁵, Soumya D Chakravarty^{5,6}, Jocelyn H Leu^{2,‡}

Fig. 4 IGA 0/1 response rates through Week 16 in pediatric participants with PsO and adults with PsO. Pediatric PsO includes patients from PRO-TOSTAR Part 1. Adult PsO includes patients from VOYAGE 1 and VOYAGE 2. IGA Investigator Global Assessment, *Ped* pediatric, *PsO* psoriasis

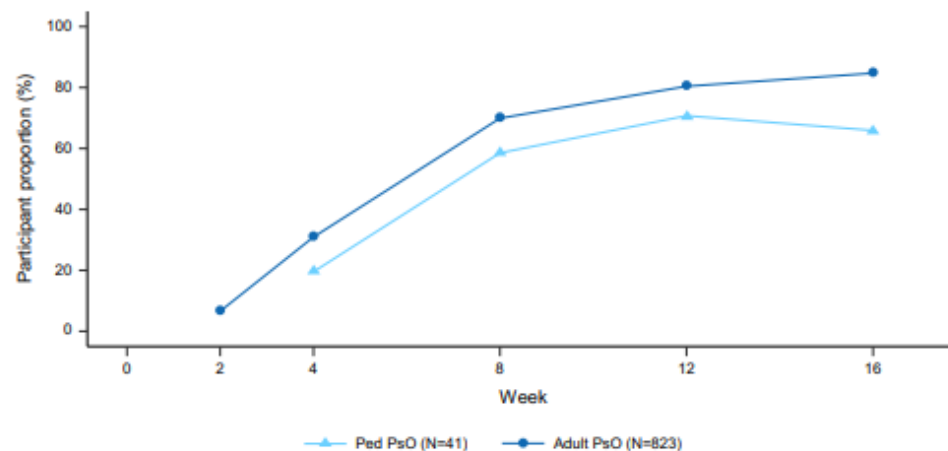


Table 2 Guselkumab safety profile in pediatric PsO participants with and without jPsA

	PsO with jPsA (<i>N</i> = 3 ^a)	PsO without jPsA (<i>N</i> = 89)	Total (<i>N</i> = 92)
Discontinued treatment	0 (0.0)	2 (2.2)	2 (2.2)
Adverse event	2 (66.7)	70 (78.7)	72 (78.3)
Serious adverse event	1 (33.3)	2 (2.2)	3 (3.3)
Any infection	2 (66.7)	50 (56.2)	52 (56.5)
Infection requiring treatment	1 (33.3)	8 (9.0)	9 (9.8)
Serious infection	0 (0.0)	0 (0.0)	0 (0.0)
Injection-site reaction	0 (0.0)	4 (4.5)	4 (4.3)

Data presented are *N* (%)

jPsA juvenile psoriatic arthritis, *PsO* psoriasis

^aTwo pediatric participants with jPsA were randomized to guselkumab at baseline, one transitioned from placebo to guselkumab at Week 16. Given the very small number of participants with jPsA (*N* = 3), percentages should be interpreted with caution and are shown for descriptive purposes only



Helpline | 800-283-7800

Your Local Area

Connect Groups

Q ES

About Arthritis

Managing Arthritis

Juvenile Arthritis

Research

Advocacy

For Providers

Get Involved

♥ DONATE MONTHLY

DONATE NOW

← Back



Jingle Bell Run®

BE THERE
WITH
BELLS ON.



Washington Family Camp

The Arthritis Foundation's Washington Family Camp provides kids with arthritis and related childhood rheumatic diseases and their families a chance to have fun, build confidence and make lasting memories together.

July 24 – 26, 2026
Auburn, WA

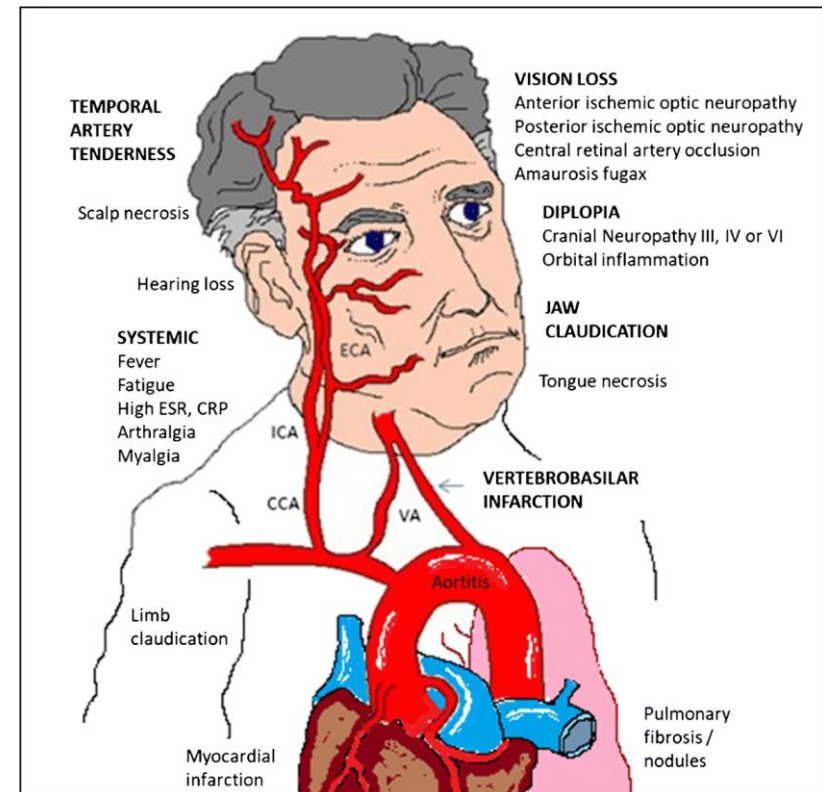
Register

Polymyalgia Rheumatica and Giant Cell Arteritis

- PMR is an inflammatory rheumatological disease second only to rheumatoid arthritis in incidence in the United States.
- The disease affects the neck, bilateral shoulders, and hip girdles/thighs.
- PMR almost never occurs in adults under age 50 and is most common between ages 70-80.
- Women are 2-3 times more likely than men to be diagnosed with PMR
- There is a genetic association in some families.
- Northern Europeans/Scandinavians tend to be most often affected (incidence of >100/100,000 in Norway versus <20/100,000 in Italy).
- PMR is 2-3 times more common than giant cell arteritis (aka, temporal arteritis)
- Giant cell arteritis is a large vessel vasculitis involving branches of the aorta or the aorta itself. Most patients with PMR will never develop giant cell arteritis, but 50% of patients with giant cell arteritis will have polymyalgia rheumatica
- Recurrence of PMR symptoms in a patient with known history of giant cell arteritis might be a sign of giant cell arteritis flare. PMR is not technically a "myositis." Rather, it involves inflammatory in the proximal joints, bursae and tendons. Ultrasound, MRI, and PET imaging showed subacromial bursitis, subdeltoid bursitis, trochanteric bursitis, iliopsoas bursitis, and synovitis of the hips.



© MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH. ALL RIGHTS RESERVED



Role of Tocilizumab (IL-6 blockade)



The NEW ENGLAND
JOURNAL of MEDICINE

CURRENT ISSUE ▼ SPECIALTIES ▼ TOPICS ▼

ORIGINAL ARTICLE



Trial of Tocilizumab in Giant-Cell Arteritis

Authors: John H. Stone, M.D., M.P.H., Katie Tuckwell, Ph.D., Sophie Dimonaco, M.Sc., Micki Klearman, M.D., Martin Aringer, M.D., Daniel Blockmans, M.D., Ph.D., Elisabeth Brouwer, M.D., Ph.D., [+8](#), and Neil Collinson, Ph.D. [Author](#)
[Info & Affiliations](#)

Published July 27, 2017 | N Engl J Med 2017;377:317-328 | DOI: 10.1056/NEJMoa1613849 | [VOL. 377 NO. 4](#)

[Copyright © 2017](#)

- Based on 52-week trial in a double-blind placebo-controlled study with 251 patients with biopsy-proven giant cell arteritis, tocilizumab 162 mg subcutaneous injection weekly was approved by the FDA for the treatment of giant cell arteritis.
- Smaller studies have shown efficacy of IV tocilizumab monthly therapy as well for giant cell arteritis, and infusion treatment might be a consideration in patients unable to obtain insurance coverage for subcutaneous tocilizumab or who cannot tolerate subcutaneous formulation.
- While tocilizumab has been shown to reduce overall prednisone intake, patients should still begin prednisone 1 mg/kg and proceed for temporal artery biopsy if there is clinical suspicion for giant cell arteritis.

- Anti-IL therapy with sarilumab has been FDA-approved for giant cell arteritis
- In 2025, upadacitinib (JAK-1 inhibitor) was FDA approved after a phase 3 trial found that a dose of 15 mg daily (but not 7.5 mg daily) was likely to lead to sustained remission when given with a 26-week glucocorticoid taper

RESEARCH SUMMARY

Sarilumab for Relapse of Polymyalgia Rheumatica during Glucocorticoid Taper

Spiers RF et al. DOI: 10.1056/NEJMoa2303452

CLINICAL PROBLEM

Polymyalgia rheumatica is typically treated with glucocorticoids, but more than half of patients cannot successfully taper treatment, resulting in long-term glucocorticoid use and substantial glucocorticoid-related morbidity. Sarilumab, a human monoclonal antibody that blocks the interleukin-6 receptor, offers another approach for the treatment of polymyalgia rheumatica.

CLINICAL TRIAL

Design: A phase 3, multicenter, double-blind, randomized, placebo-controlled trial evaluated the efficacy and safety of sarilumab in patients with polymyalgia rheumatica that flared with glucocorticoid taper.

Intervention: 118 symptomatic patients who had had ≥1 disease flare during prednisone taper in the previous 12 weeks were assigned in a 1:1 ratio to receive 52 weeks of a twice-monthly subcutaneous injection of either sarilumab (at a dose of 200 mg) plus a 14-week prednisone taper or placebo plus a 52-week prednisone taper. The primary outcome was sustained remission at 52 weeks; sustained remission was defined as clinical remission by week 12 and absence of disease flare, sustained C-reactive protein normalization, and adherence to prednisone taper from weeks 12 to 52.

RESULTS

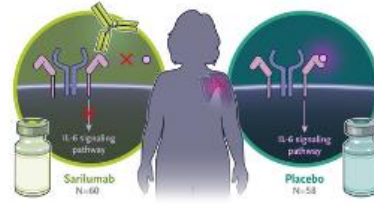
Efficacy: The proportion of patients with sustained remission at 52 weeks in the sarilumab group was nearly three times that in the placebo group.

Safety: Neutropenia, arthralgia, and diarrhea were among the most common adverse events and occurred more often in the sarilumab group than in the placebo group. Treatment discontinuation because of adverse events was also more common with sarilumab.

LIMITATIONS AND REMAINING QUESTIONS

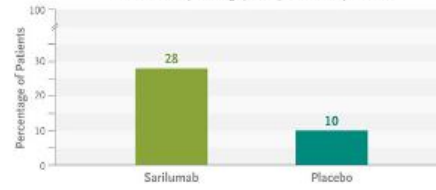
- Enrollment was stopped early because of the Covid-19 pandemic. (Planned enrollment was 280.)
- The safety analysis was limited by the small sample size.

Links: Full Article | NEJM Quick Take | Editorial



Sustained Remission at 52 Wk

Difference, 18 percentage points (95% CI, 4–32); P=0.02



Safety



CONCLUSIONS

In patients with a relapse of polymyalgia rheumatica during prednisone taper, treatment with the human monoclonal antibody sarilumab showed significant efficacy in achieving sustained remission and reducing the cumulative glucocorticoid dose.

A Phase 3 Trial of Upadacitinib for Giant-Cell Arteritis

A Research Summary based on Blockmans D et al. | 10.1056/NEJMoa2413449 | Published on April 2, 2025

WHY WAS THE TRIAL DONE?

For patients with giant-cell arteritis, there is an unmet need for effective, glucocorticoid-sparing treatments. Upadacitinib, an oral, selective Janus kinase (JAK)-1 inhibitor, has the potential to block multiple pathogenic pathways in giant-cell arteritis and has been approved to treat several immune-mediated inflammatory diseases. Data on the efficacy and safety of upadacitinib in giant-cell arteritis are lacking.

HOW WAS THE TRIAL CONDUCTED?

Adults 50 years of age or older with new-onset or relapsing giant-cell arteritis were assigned to receive upadacitinib at a dose of 15 mg or 7.5 mg orally once daily plus a 26-week glucocorticoid taper or placebo plus a 52-week glucocorticoid taper. The primary end point was sustained remission at week 52, defined by the absence of signs or symptoms of giant-cell arteritis from week 12 through week 52 and by adherence to the protocol-specified glucocorticoid taper.

TRIAL DESIGN

- Phase 3
- Randomized
- Placebo-controlled
- Superiority
- Location: 100 sites in 24 countries

RESULTS

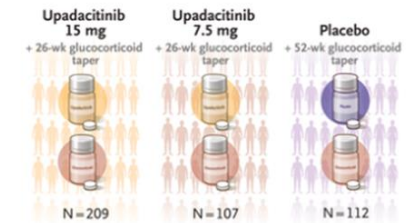
At week 52, the percentage of patients with sustained remission was significantly higher with the 15-mg dose of upadacitinib plus a 26-week glucocorticoid taper than with placebo plus a 52-week glucocorticoid taper. The 7.5-mg dose of upadacitinib plus a 26-week glucocorticoid taper was not superior to the placebo regimen. Safety outcomes were generally similar across the groups. The incidence of overall adverse events and of serious adverse events over the course of 52 weeks was similar in patients receiving 15-mg upadacitinib and in those receiving placebo.

LIMITATIONS AND REMAINING QUESTIONS

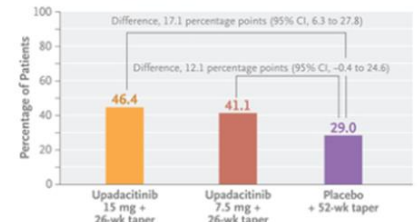
- A higher-than-expected percentage of patients discontinued upadacitinib (26%) or placebo (37%).
- Efficacy among the patients for whom interleukin-6 inhibition was not assessed.

Patients

- 428 adults
- Mean age: 71 years
- Women: 73%; Men: 27%



Sustained Remission at Week 52



Recommendations of the German, Austrian and Swiss rheumatology and other medical societies for the management of polymyalgia rheumatica

Frank Buttgereit , Zhivana Boyadzhieva, Myriam Reisch, Matthias Schneider, Thomas Brabant, Thomas Daikeler, Christina Duftner, Ulrike Erstling, Ute Garske, Bernhard Hellmich ... [Show more](#)

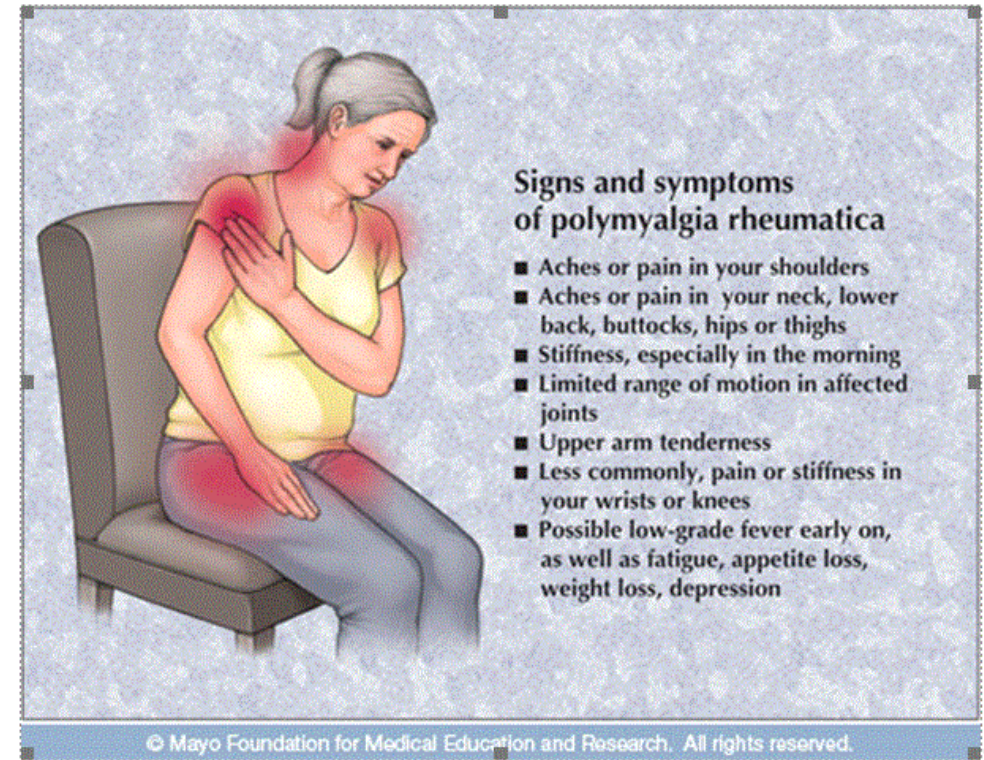
[Author Notes](#)

Rheumatology, Volume 65, Issue 2, February 2026, keaf646,

<https://doi.org/10.1093/rheumatology/keaf646>

Published: 04 December 2025 **Article history** ▼

- Three European nation consortium of rheumatological societies updated recommendations for management of PMR
- Key Points: use prednisone 15-25 mg daily as initial therapy for PMR, followed by 12-month taper
- For patients at risk of relapsing PMR or high risk of glucocorticoid-related side effects, begin concurrent IL-6 inhibitor therapy with goal of tapering prednisone in four months if possible
- Recommendations in line with American College of Rheumatology



Miscellaneous

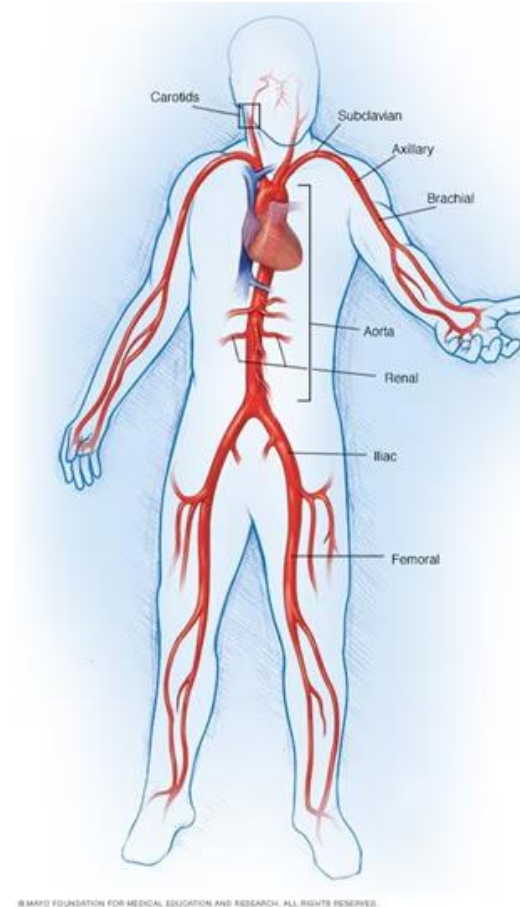
Results of a 1-year randomised double-blind placebo-controlled trial with methotrexate 25 mg/week in recently diagnosed polymyalgia rheumatica

Thomas E. Bolhuis^{1,2†}, Noortje E.S.E.P. Kooijman^{1,2†}, Diane E. Marsman¹, Gijs F. Snijders³,
Alfons A. den Broeder^{1,4}, Nathan den Broeder^{1,2}, Aatke van der Maas¹  

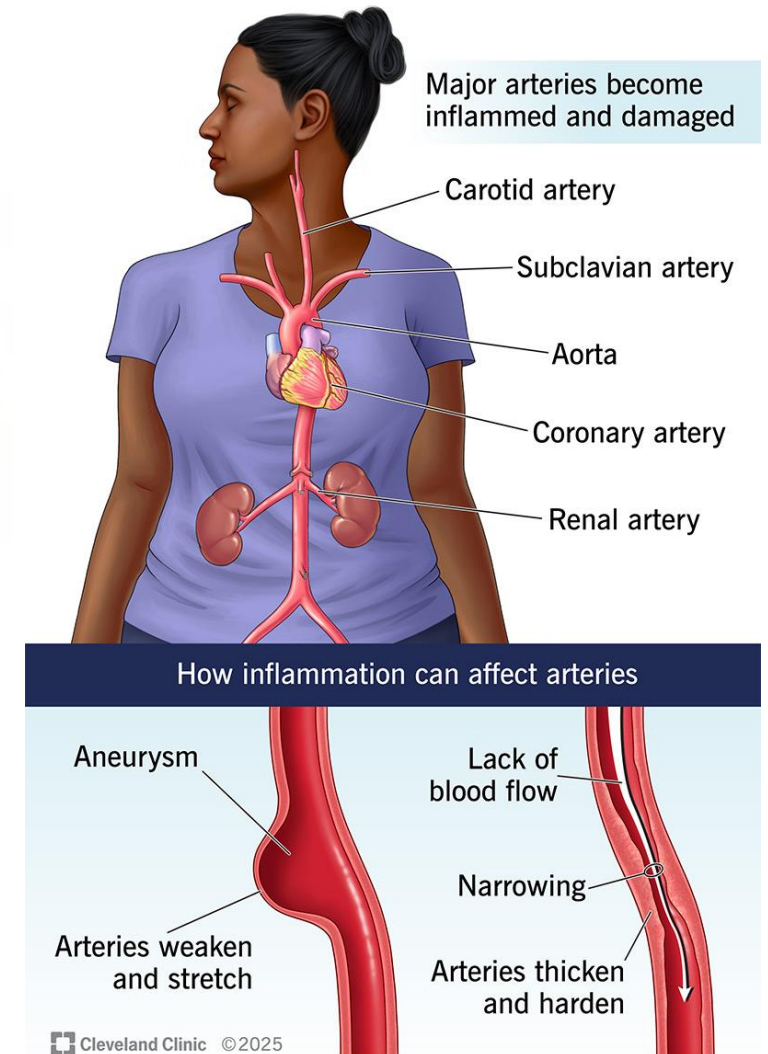
- In a trial of 58 patients with newly-diagnosed PMR, substantially more patients achieved steroid-free remission at 52 weeks when treated with methotrexate 25 mg weekly dose plus a 24-week steroid taper compared to steroids alone (80% vs 46%)
- The cumulative dose of glucocorticoids used by both groups was similar
- Low dose methotrexate (7.5-10 mg weekly) produced equivocal results
- Key Point: This is a small study, but early initiation of high dose methotrexate might lead to glucocorticoid-free remission in PMR patients

Takayasu arteritis

- Rare chronic large vessel vasculitis commonly affecting women of East Asian ancestry but seen in all sexes and ethnicities
- Often referred to as “pulseless disease,” systemic inflammation can lead to constitutional symptoms, chest pain, fainting, dizziness, weight loss, fatigue, claudication and aneurysm formation
- No FDA-approved DMARD therapies to date



Takayasu's arteritis *Pulseless disease*





Volume 64, Issue 12
December 2025

Comments (0)

JOURNAL ARTICLE

Effectiveness of intravenous infliximab versus subcutaneous adalimumab in Takayasu arteritis: a multicentre retrospective study

[Get access >](#)

Arsène Mekinian ✉, Sarah Meneses, Lucie Biard, Lorenzo Dagna, Pavel Novikov, Carlo Salvarani, Olivier Espitia, Savino Sciscia, Martin Michaud, Marc Lambert ... [Show more](#)

Rheumatology, Volume 64, Issue 12, December 2025, Pages 6192–6200,
<https://doi.org/10.1093/rheumatology/keaf341>

Published: 14 August 2025 [Article history](#) ▼

- In a retrospective review of 135 patients treated with TNF inhibitors, subcutaneous adalimumab and IV infliximab achieved similar complete response rates at 6 months (68% vs 73%) with similar rates of relapse at 12 months, treatment failure, and revascularization
- While cyclophosphamide has historically been used for aggressive or fulminant Takayasu arteritis, a randomized trial of 111 patients compared mycophenolate mofetil (MMF) plus methotrexate (MTX) compared to cyclophosphamide induction followed by azathioprine. Complete and partial response rates were greater with MMF + MTX at both 28 and 52 weeks. Serious adverse events were rare in both groups.
- In 10 young women with Takayasu arteritis who had failed TNF inhibitor therapy, 80% of patients had clinical response to baricitinib (a JAK inhibitor) at 24 weeks (including 6 complete response and 2 partial response)



► *Rheumatology (Oxford)*. 2025 May 24;64(10):5262–5268. doi: [10.1093/rheumatology/keaf286](https://doi.org/10.1093/rheumatology/keaf286) [↗](#)

Baricitinib for Takayasu arteritis refractory to TNF-α inhibitors: a multicentre, single-arm trial

[Jiachen Li](#)^{1,*}, [Weiyi Xia](#)^{2,*}, [Huijuan Ji](#)³, [Xiaoxin Gong](#)⁴, [Qi Dong](#)⁵, [Yanan Wu](#)⁶, [Longjun Wang](#)⁷, [Meixia Peng](#)⁸, [Jingxuan Liu](#)⁹, [Ke Ma](#)¹⁰, [Qi Yu](#)¹¹, [Xinglei Cui](#)¹², [Yuanyuan Luo](#)¹³, [Wenhua Zhu](#)¹⁴, [Shumin Zhang](#)¹⁵, [Shi Chen](#)¹⁶, [Yuhui Li](#)^{17,18}, [Zhanguo Li](#)¹⁹, [Tian Liu](#)^{20,21,✉}



Annals of the Rheumatic Diseases
Volume 84, Issue 10, October 2025, Pages 1733–1742



Vasculitis

Mycophenolate mofetil plus methotrexate versus cyclophosphamide with sequential azathioprine for treatment of Takayasu arteritis

[Xiaochuan Sun](#)¹, [Jing Li](#)², [Xinwang Duan](#)³, [Yahong Wang](#)⁴, [Yu Chen](#)⁵, [Ying Wang](#)⁴, [Liyun Zhang](#)⁶, [Dongyun Yao](#)⁷, [Jing Xue](#)⁸, [Zhenbiao Wu](#)⁹, [Yi Zhao](#)¹⁰, [Li Luo](#)¹¹, [Hongfeng Zhang](#)¹², [Xiuling Zhang](#)³, [Lili Pan](#)¹³, [Xiaofeng Zeng](#)², [Mengtao Li](#)² ✉, [Peter A. Merkel](#)¹⁴ ✉, [Xinping Tian](#)² ✉

Key point – we have more evidence behind DMARD therapies for Takayasu arteritis than ever before

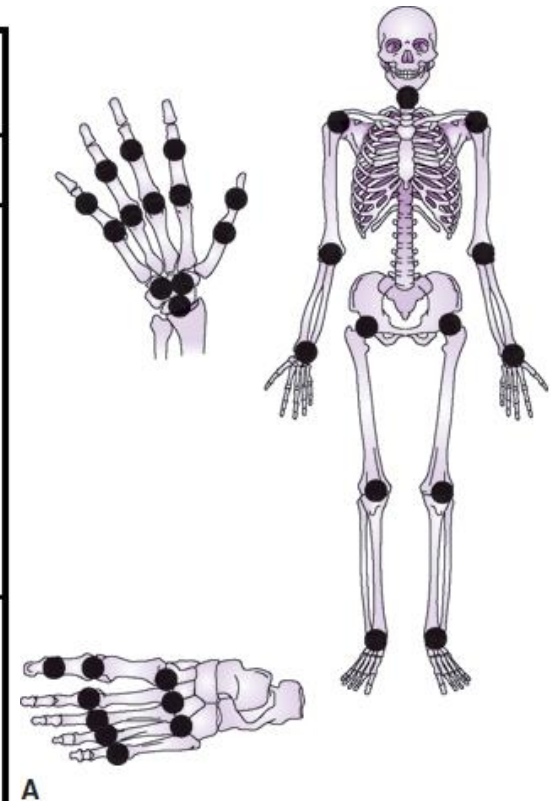
Rheumatoid Arthritis Updates

Target population: Patients who (i) have at least 1 joint with clinical synovitis and (ii) with the synovitis not better explained by another disease.

	Score
A. Joint involvement (tender/swollen)	
1 large joint	0
2-10 large joints	1
1-3 small joints (± involvement of large joints)	2
4-10 small joints (± involvement of large joints)	3
> 10 joints (at least 1 small joint)	5
B. Serology	
Negative RF & ACPA	0
Low-positive RF/low-positive ACPA	2
High-positive RF/high-positive ACPA	3

	Score
C. Acute-phase reactants	
Normal CRP & ESR	0
Abnormal CRP & ESR	1
D. Duration of symptoms	
< 6 weeks	0
≥ 6 weeks	1

Add score of categories A-D:
≥ 6/10 = definite RA



A
 Source: Imboden JB, Hellmann DB, Stone JH: *Current Diagnosis & Treatment: Rheumatology*, 3rd Edition: www.accessmedicine.com

Copyright © The McGraw-Hill Companies, Inc. All rights reserved.

2010 ACR/EULAR Classification criteria for RA¹. ACR: American College of Rheumatology; EULAR: European League Against Rheumatism; RF: rheumatoid factor; ACPA: anticitrullinated protein antibodies; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; RA: rheumatoid arthritis. From Aletaha, et al. *Ann Rheum Dis* 2010;69:1580–8; with permission.

Rheumatoid Arthritis Updates

Updates to ORAL surveillance trial (2022)

- Patients with rheumatoid arthritis are at increased risk of cardiovascular disease but often do not receive ample CVD prevention measures such as treatment with statins
- ORAL Surveillance indicated that patients with RA aged ≥ 50 years and ≥ 1 additional cardiovascular (CV) risk factor have an increased occurrence of major adverse CV events (MACE) with **tofacitinib** compared with tumour necrosis factor inhibitors (TNFi).
- In all treatment arms, participants with a history of atherosclerotic CVD (ASCVD) had higher rates of MACE compared with those with no history of ASCVD. **The difference in risk of MACE with tofacitinib vs TNFi was mainly apparent in participants who had a history of ASCVD.**

Ann Rheum Dis 85 (2026) 103–113

Contents lists available at ScienceDirect

Annals of the Rheumatic Diseases

journal homepage: <https://www.sciencedirect.com/journal/annals-of-the-rheumatic-diseases>

Rheumatoid arthritis

Use of statins and its association with major adverse cardiovascular events with tofacitinib vs TNF inhibitors in patients with rheumatoid arthritis with and without atherosclerotic cardiovascular disease

Jon T. Giles^{1,*}, Christina Charles-Schoeman², Maya H. Buch³, Maxime Dougados^{4,5,6,7}, Zoltán Szekanecz⁸, Ted R. Mikuls⁹, Steven R. Ytterberg¹⁰, Gary G. Koch¹¹, Kenneth Kwok¹², Mary Jane Cadatal¹³, Sujatha Menon¹⁴, Yan Chen¹⁵, Annette M. Diehl¹⁵, Jose L. Rivas¹⁶, Arne Yndestad¹⁷, Deepak L. Bhatt¹⁸

¹ Division of Rheumatology and Kao Autoimmunity Institute, Cedars Sinai Medical Center, Los Angeles, CA, USA
² Division of Rheumatology, Department of Medicine, University of California, Los Angeles, CA, USA
³ Centre for Musculoskeletal Research, Division of Musculoskeletal and Dermatological Sciences, Faculty of Biology, Medicine and Health, University of Manchester, and NIHR Manchester Biomedical Research Centre, Manchester, UK
⁴ Université de Paris, Paris, France
⁵ Department of Rheumatology, Hôpital Cochin, Paris, France
⁶ Assistance Publique-Hôpitaux de Paris, Paris, France
⁷ INSERM (U1153): Clinical Epidemiology and Biostatistics, PRES Sorbonne Paris-Cité, Paris, France
⁸ Department of Rheumatology, Faculty of Medicine, University of Debrecen, Debrecen, Hungary
⁹ Division of Rheumatology and Immunology, University of Nebraska Medical Center and VA Nebraska Western Iowa Health Care System, Omaha, NE, USA
¹⁰ Division of Rheumatology, Mayo Clinic, Rochester, MN, USA
¹¹ Department of Biostatistics, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
¹² Pfizer Inc, New York, NY, USA
¹³ Pfizer Inc, Manila, Philippines
¹⁴ Pfizer Inc, Groton, CT, USA
¹⁵ Pfizer Inc, Collegeville, PA, USA
¹⁶ Pfizer SLU, Madrid, Spain
¹⁷ Pfizer Inc, Oslo, Norway
¹⁸ Mount Sinai Fuster Heart Hospital, Icahn School of Medicine at Mount Sinai, New York, NY, USA

ARTICLE INFO ABSTRACT

Use of statins and its association with major adverse cardiovascular events with tofacitinib vs TNF inhibitors in patients with rheumatoid arthritis with and without atherosclerotic cardiovascular disease

2026 Updates to **ORAL** surveillance trial

- A new analysis of the ORAL surveillance trial suggests the **increased risk of major adverse cardiac events (MACE)** among patients ≥ 50 years old and with ≥ 1 cardiac risk factor in the tofacitinib group reported in the original study **is impacted by statin therapy**
- Among patients with prior atherosclerotic cardiovascular disease who never used statins, the risk of MACE was higher with tofacitinib than with TNF inhibitors (hazard ratio [HR] 4.1); however, the **risk was nonsignificant among those using statins at baseline or during follow-up (HR 1.2, 95% CI -.5-3.0)**.
- These findings suggest that using statins may mitigate the risk of MACE associated with the use of tofacitinib. However, the higher risk of cancer and serious infection in selected patients receiving tofacitinib remains an important consideration.



Carpal Tunnel Syndrome as an Early Underrecognized Feature of Rheumatoid Arthritis

1,335 patients with RA diagnosed between 1980 to 2019 matched 1:1 with individuals without RA.

Found more than two-fold increase in risk of CTS in the years preceding RA and a 1.8-fold increased risk of incident CTS following RA onset.

Most previous incidences of CTS occurred ≥ 2 years before the index date.

Following RA dx 80%-higher risk of CTS (hazard ratio [HR] 1.78; 95% CI 1.38–2.30). The risk estimates of CTS in patients with seronegative (vs seropositive) RA were OR 1.33 (95% CI 0.96–1.84)

George RJ. Carpal Tunnel Syndrome as an Early Underrecognized Feature of Rheumatoid Arthritis: A Population-Based Study of Carpal Tunnel Syndrome Occurrence Before and After Rheumatoid Arthritis Incidence. *Arthritis Care Res* (Hoboken). 2025 Nov;77(11):1332-1339. doi: 10.1002/acr.25566. Epub 2025 Jun 16. PMID: 40322852; PMCID: PMC12353601.

© 2014 Virginia Mason Medical Center



AMERICAN COLLEGE
of RHEUMATOLOGY
Empowering Rheumatology Professionals

Arthritis Care & Research
Vol. 77, No. 11, November 2025, pp 1332-1339
DOI: 10.1002/acr.25566
© 2025 American College of Rheumatology

Carpal Tunnel Syndrome as an Early Underrecognized Feature of Rheumatoid Arthritis: A Population-Based Study of Carpal Tunnel Syndrome Occurrence Before and After Rheumatoid Arthritis Incidence

Roslin Jose George, Noah Frechette, Manuela Oviedo, Iqra Javed, Sara J. Achenbach, Ryan J. Lennon, Bradley Alex Kimbrough, Elena K. Joerns, Vanessa L. Kronzer, Anne Gingery, John M. Davis III, Cynthia S. Crowson, and Elena Myasoedova

Objective. We aimed to assess the occurrence of carpal tunnel syndrome (CTS) before and after rheumatoid arthritis (RA) incidence and by serologic status.

Methods. This population-based study included residents of a geographically defined area meeting the 1987 American College of Rheumatology classification criteria for RA in 1980 to 2019 matched 1:1 with individuals without RA. At least two diagnosis codes ≥ 30 days apart were used to identify CTS. Cumulative incidence of CTS adjusting for competing risk of death was assessed. Logistic regression and Cox proportional hazard models were used, adjusting for age, sex, calendar year, smoking, obesity, diabetes mellitus, and hypothyroidism.

Results. We included 1,335 patients with RA and 1,331 individuals without RA. The overall prevalence of CTS before or on RA incidence or index was 179 patients with RA (13%) and 85 individuals without RA (6%), respectively (odds ratio [OR] 2.23; 95% confidence interval [CI] 1.69–2.94). Most previous incidences of CTS occurred ≥ 2 years before the index date (112 events in patients with RA and 75 events in individuals without RA, respectively). Following RA incidence or index, individuals with RA (vs those without RA) had $\sim 80\%$ -higher risk of CTS (hazard ratio [HR] 1.78; 95% CI 1.38–2.30). The risk estimates of CTS in patients with seronegative (vs seropositive) RA were OR 1.33 (95% CI 0.96–1.84) before RA incidence and HR 1.37 (95% CI 0.99–1.88) after RA incidence. In RA, obesity (HR 1.42, 95% CI 1.02–1.99) and seronegative cyclic citrullinated peptide antibody status (HR 1.79, 95% CI 1.07–2.99), but not other risk factors, were associated with increased CTS risk.

Conclusion. We found a more than two-fold increase in risk of CTS in the years preceding RA and a 1.8-fold increased risk of incident CTS following RA onset.

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common peripheral nerve entrapment syndrome, with multifactorial etiology and an estimated prevalence of approximately 1% to 5%. Characterized by progressive fibrosis of the subsynovial connective tissue, resulting

in compression or entrapment of the median nerve, CTS is more prevalent among the middle aged to older adult population and impacts twice as many women as men.^{2–4} CTS is associated with several chronic conditions (eg, hypothyroidism, diabetes mellitus [DM]).^{5–7} Among the various risk factors, inflammatory processes have also been associated with the pathology and severity of CTS.^{8,9}

The content of this article is solely the responsibility of the authors and does not represent the official views of the NIH or the Mayo Clinic.

Supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH (grants R01-AR-46849, R01-AR-076347, and R01-AR-

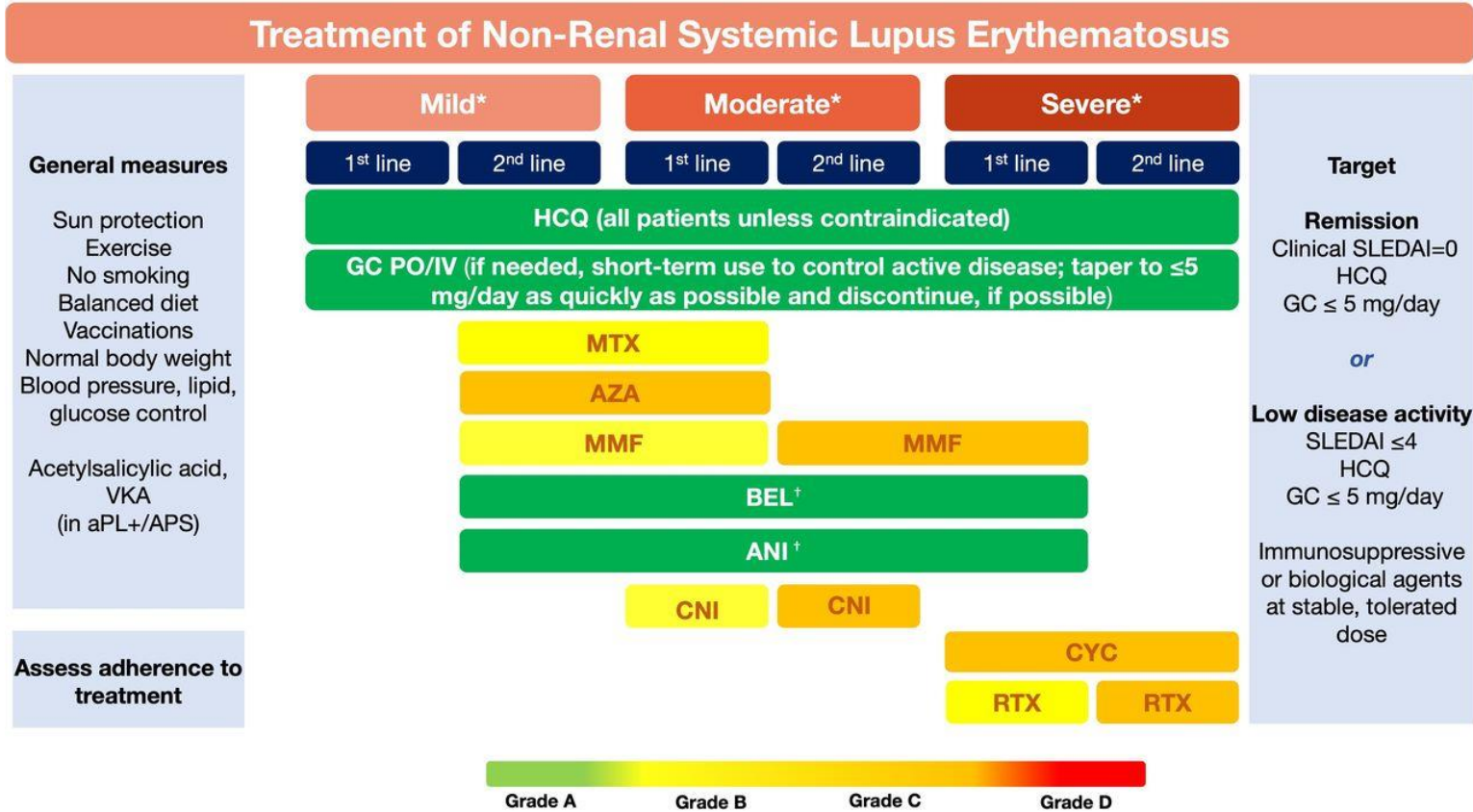
L. Kronzer, MD, MScI, Anne Gingery, PhD, John M. Davis III, MD, MS, RhMSUS, Cynthia S. Crowson, PhD, Elena Myasoedova, MD, PhD: Mayo Clinic, Rochester, Minnesota.

Additional supplementary information cited in this article can be found

Entry criterion			
antinuclear antibodies (ANA) at a titer of $\geq 1:80$ on HEp-2 cells or an equivalent positive test (ever)			
↓			
If absent, do not classify as SLE			
If present, apply additive criteria			
↓			
Additive criteria			
Do not count a criterion if there is a more likely explanation than SLE.			
Occurrence of a criterion on at least one occasion is sufficient.			
SLE classification requires at least one clinical criterion and ≥ 10 points.			
Criteria need not occur simultaneously.			
Within each domain, only the highest weighted criterion is counted toward the total score.			
Clinical domains and criteria	Weight	Immunology domains and criteria	Weight
Constitutional		Antiphospholipid antibodies	
Fever	2	Anti-cardiolipin antibodies OR	
Hematologic		Anti- $\beta 2$ GP1 antibodies OR	
Leukopenia	3	Lupus anticoagulant	2
Thrombocytopenia	4	Complement proteins	
Autoimmune hemolysis	4	Low C3 OR low C4	3
Neuropsychiatric		Low C3 AND low C4	4
Delirium	2	SLE-specific antibodies	
Psychosis	3	Anti-dsDNA antibody* OR	
Seizure	5	Anti-Smith antibody	6
Mucocutaneous			
Non-scarring alopecia	2		
Oral ulcers	2		
Subacute cutaneous OR discoid lupus	4		
Acute cutaneous lupus	6		
Serosal			
Pleural or pericardial effusion	5		
Acute pericarditis	6		
Musculoskeletal			
Joint involvement	6		
Renal			
Proteinuria $>0.5\text{g}/24\text{h}$	4		
Renal biopsy Class II or V lupus nephritis	8		
Renal biopsy Class III or IV lupus nephritis	10		
Total score:			
↓			
Classify as Systemic Lupus Erythematosus with a score of 10 or more if entry criterion fulfilled.			

Aringer M, Costenbader K, Daikh D, et al. Ann Rheum Dis 2019;78:1151-1159.

SLE Updates



Fanouriakis A, Kostopoulou M, Andersen J, et al/EULAR recommendations for the management of systemic lupus erythematosus: 2023 updateAnnals of the Rheumatic Diseases 2024;83:15-29.

SLE Updates

Anti-CD20 monoclonal antibody

The FDA approved obinutuzumab (brand name Gazyva) on **October 20, 2025**, for the treatment of adult patients with active **lupus nephritis**

303 patients with active SLE without proliferative or membranous LN were randomly assigned to receive placebo or obinutuzumab (two dose of 1000 mg given two weeks apart, and repeated after 24 weeks).

Compared with the placebo group, the obinutuzumab group had greater improvements in multiple measures after 52 weeks, including ones in global disease activity (as measured by BICLA response, 40 versus 62 percent, respectively), glucocorticoid-sparing effects, and time to SLE flare.

No new safety signals related to obinutuzumab were observed.

This study suggests that obinutuzumab is effective for treating non-renal manifestations of SLE.

ORIGINAL ARTICLE

Efficacy and Safety of Obinutuzumab in Active Systemic Lupus Erythematosus

R.A. Furie,^{1,2} M. Dall'Era,³ E.M. Vital,^{4,5} J.P. Garg,⁶ F. Irazoque Palazuelos,⁷ A.E. Zuta Santillán,⁸ J. Ravelo-Hernández,⁹ M.B. Santiago,^{10,12} B. Zazueta Montiel,¹³ S. Botha,¹⁴ P. Leszczyński,¹⁵ V.A. de Souza,¹⁶ S.A. Sicsik,¹⁷ L. Bellatin,¹⁸ A. Naidoo,¹⁹ Z. Amoura,²⁰ M.A. D'Agostino,^{21,22} S. Kumar,²³ B. Workeneh,²⁴ J. Rae,⁶ H.A. Mao,²⁵ F. Erblang,²⁶ O. Meier,²⁶ J.C. Maller,⁶ and A.D. Askanase,²⁷ for the ALLEGORY Trial Investigators*

ABSTRACT

BACKGROUND

Obinutuzumab, a glycoengineered type II anti-CD20 monoclonal antibody, induces potent B-cell depletion and is approved for the treatment of active lupus nephritis. Its efficacy and safety in patients with active systemic lupus erythematosus (SLE) are yet to be determined.

METHODS

We conducted a phase 3, multicenter, double-blind, placebo-controlled trial involving adults with active SLE but without proliferative or membranous lupus nephritis who were receiving standard therapy. Patients were randomly assigned in a 1:1 ratio to receive obinutuzumab (1000 mg) or placebo on day 1 and weeks 2, 24, and 26. In the prespecified analysis, the primary end point at week 52 was a response on the SLE Responder Index 4 (SRI-4), defined by a reduction from baseline of at least 4 points in the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score, no worsening of disease as assessed by the British Isles Lupus Assessment Group (BILAG) 2004 index and Physician's Global Assessment, and no intercurrent events (i.e., major concomitant-therapy violation, receipt of rescue medication, or early discontinuation of trial participation due to death, lack of efficacy, or adverse events).

RESULTS

Of 303 patients who underwent randomization, 151 were assigned to receive obinutuzumab and 152 to receive placebo. At week 52, an SRI-4 response was observed in 76.7% of the patients in the obinutuzumab group and in 53.5% of those in the placebo group (adjusted difference, 23.1 percentage points; 95% confidence interval [CI], 12.5 to 33.6; $P < 0.001$). In an additional analysis whereby nonfatal intercurrent events did not affect response status, the respective percentages were 85.4%

The authors' full names, degrees, and affiliations of the article. Richard A. Furie, MD, Division of Rheumatology, 865 Northern Blvd., NY 11021

*A complete list of the ALLEGORY trial is in the Supplementary Appendix.

This article was published in 2026, and last updated at NEJM.org.

DOI: 10.1056/NEJM
Copyright © 2026 Mass

SLE Updates

The NEW ENGLAND JOURNAL of MEDICINE

Table 3. Adverse Events through Week 52 (Safety Population).*

Event	Obinutuzumab (N=151)	Placebo (N=151)
Any adverse event — no. (%)	134 (88.7)	123 (81.5)
Total no. of adverse events	568	468
Any serious adverse event — no. (%)	24 (15.9)	18 (11.9)
Deaths — no. (%)	1 (0.7)	3 (2.0)
Adverse event leading to withdrawal from trial — no. (%)	1 (0.7)	2 (1.3)
Adverse event of grade 3 or higher — no. (%)	25 (16.6)	21 (13.9)
Infection — no. (%)	103 (68.2)	82 (54.3)
Infection as a serious adverse event — no. (%)	13 (8.6)	7 (4.6)
Adverse event with fatal outcome — no. (%)†	1 (0.7)	5 (3.3)
Adverse event leading to discontinuation of obinutuzumab or placebo — no. (%)	6 (4.0)	6 (4.0)
Serious adverse event leading to discontinuation of obinutuzumab or placebo — no. (%)	3 (2.0)	3 (2.0)
Infusion-related reaction — no. (%)	18 (11.9)	5 (3.3)
Infection of grade 3 or higher — no. (%)	11 (7.3)	7 (4.6)
Any hepatitis B reactivation or progressive multifocal leukoencephalopathy — no. (%)	0	0
Drug-related neutropenia — no. (%)	7 (4.6)	3 (2.0)
Drug-related thrombocytopenia — no. (%)	0	0
Gastrointestinal perforation — no. (%)	0	1 (0.7)
Worsening of preexisting cardiac condition — no. (%)	0	0
Potential drug-induced liver failure meeting Hy's law criteria — no. (%)	0	1 (0.7)
Suspected transmission of an infectious agent by obinutuzumab or placebo — no. (%)	0	0

* One patient assigned to the placebo group did not receive placebo and was subsequently excluded from the safety analysis. Multiple occurrences of the same adverse event in the same patient were counted only once, except for "Total no. of adverse events," in which multiple occurrences of the same adverse event were counted separately. Included are adverse events until the time of rescue for patients who received rescue therapy.

† Two deaths in the placebo group occurred after week 52, but the adverse events started during the 52-week blinded period.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Efficacy and Safety of Obinutuzumab in Active Systemic Lupus Erythematosus

R.A. Furie,^{1,2} M. Dall'Era,³ E.M. Vital,^{4,5} J.P. Garg,⁶ F. Irazoque Palazuelos,⁷ A.E. Zuta Santillán,⁸ J. Ravelo-Hernández,⁹ M.B. Santiago,^{10,12} B. Zazueta Montiel,¹³ S. Botha,¹⁴ P. Leszczyński,¹⁵ V.A. de Souza,¹⁶ S.A. Sicsik,¹⁷ L. Bellatin,¹⁸ A. Naidoo,¹⁹ Z. Amoura,²⁰ M.A. D'Agostino,^{21,22} S. Kumar,²³ B. Workeneh,²⁴ J. Rae,⁶ H.A. Mao,²⁵ F. Erblang,²⁶ O. Meier,²⁶ J.C. Maller,⁶ and A.D. Askanase,²⁷ for the ALLEGORY Trial Investigators*

ABSTRACT

BACKGROUND

Obinutuzumab, a glycoengineered type II anti-CD20 monoclonal antibody, induces potent B-cell depletion and is approved for the treatment of active lupus nephritis. Its efficacy and safety in patients with active systemic lupus erythematosus (SLE) are yet to be determined.

METHODS

We conducted a phase 3, multicenter, double-blind, placebo-controlled trial involving adults with active SLE but without proliferative or membranous lupus nephritis who were receiving standard therapy. Patients were randomly assigned in a 1:1 ratio to receive obinutuzumab (1000 mg) or placebo on day 1 and weeks 2, 24, and 26. In the prespecified analysis, the primary end point at week 52 was a response on the SLE Responder Index 4 (SRI-4), defined by a reduction from baseline of at least 4 points in the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score, no worsening of disease as assessed by the British Isles Lupus Assessment Group (BILAG) 2004 index and Physician's Global Assessment, and no intercurrent events (i.e., major concomitant-therapy violation, receipt of rescue medication, or early discontinuation of trial participation due to death, lack of efficacy, or adverse events).

RESULTS

Of 303 patients who underwent randomization, 151 were assigned to receive obinutuzumab and 152 to receive placebo. At week 52, an SRI-4 response was observed in 76.7% of the patients in the obinutuzumab group and in 53.5% of those in the placebo group (adjusted difference, 23.1 percentage points; 95% confidence interval [CI], 12.5 to 33.6; $P < 0.001$). In an additional analysis whereby nonfatal intercurrent events did not affect response status, the respective percentages were 85.4%

The authors' full names, degrees, and affiliations of the article. Richard Furie, MD, Division of Rheumatology, 865 Northern Blvd., NY 11021

*A complete list of the ALLEGORY trial investigators is in the Supplementary Appendix.

This article was published online on June 1, 2026, and last updated on June 1, 2026, at NEJM.org.

DOI: 10.1056/NEJMoa2508000
Copyright © 2026 Massachusetts Medical Society

Approval Date	Medication (Brand Name)	Generic Name	Approved Indications	Method of Administration
1948	Aspirin	Aspirin	Systemic Lupus Erythematosus (Arthritic symptoms)	Oral tablet
1955	Plaquenil	Hydroxychloroquine	Systemic Lupus Erythematosus	Oral tablet
1955	Corticosteroids	Prednisone / Methylprednisolone	Systemic Lupus Erythematosus & Lupus Nephritis	Oral, IV, or IM
March 2011	Benlysta	Belimumab	Systemic Lupus Erythematosus	IV Infusion
December 2020	Benlysta	Belimumab	Lupus Nephritis	IV Infusion or Subcutaneous injection
January 2021	Lupkynis	Voclosporin	Active Lupus Nephritis	Oral capsule
August 2021	Saphnelo	Anifrolumab-fnia	Moderate to Severe Systemic Lupus Erythematosus	IV Infusion
Late 2025 / Early 2026	Saphnelo	Anifrolumab-fnia	Moderate to Severe Systemic Lupus Erythematosus	Subcutaneous injection

Sjogrens Updates

1. The term *Sjögren's Disease* should replace *Sjögren's Syndrome*.
2. *Sjögren's* without *disease* is an acceptable way to refer to the disease, especially once it's been cited as *Sjögren's Disease*.
3. The acronym *SjD* should be used as an abbreviation for *Sjögren's Disease*.
4. The descriptor *associated* should be used in lieu of *secondary* for Sjögren's Disease occurring in association with a second systemic autoimmune disease for which classification criteria are fulfilled.
5. *Sjögren Disease* is the preferred terminology in clinical practice, without differentiation as to primary and associated forms. An appreciation of the common association of Sjögren's with other systemic autoimmune diseases may have value in clinical evaluation of affected patients and in clinical decision-making.
6. The differentiation between *primary* and *associated* Sjögren's is recommended for scientific studies to define a homogeneous population.
7. The choice of using the possessive or non-possessive form of Sjögren's and spelling variants (o, oe, ö), should be left to the individual or journal preference.

2023 International Rome consensus for the nomenclature of Sjögren disease

Manuel Ramos-Casals^{1,2,96}, Alan N. Baer^{3,96}✉, María del Pilar Brito-Zerón⁴, Katherine M. Hammitt⁵, Coralie Bouillot⁶, Soledad Retamozo⁷, Alison Mackey⁸, David Yarowsky⁹, Breck Turner¹⁰, Jaime Blanck¹⁰, Benjamin A. Fisher^{11,12,13}, Esen K. Akpek¹⁴, Chiara Baldini¹⁵, Hendrika Bootsma¹⁶, Simon J. Bowman^{11,13,17,18}, Thomas Dörner¹⁹, Leslie Laing^{20,21}, Scott M. Lieberman²², Xavier Mariette²³, Stephen C. Pflugfelder²⁴, Vidya Sankar²⁵, Antoni Sisó-Almirall^{2,26,27}, Athanasios G. Tzioufas^{28,29}, Juan-Manuel Anaya³⁰, Berkan Armağan³¹, Michele Bombardieri³², Steven Carsons³³, Salvatore de Vita^{34,35,95}, Robert I. Fox³⁶, Roberto Gerli³⁷, Roberto Giacomelli^{38,39}, Jacques Eric Gottenberg⁴⁰, Gabriela Hernández-Molina⁴¹, Roland Jonsson⁴², Aike Kruize⁴³, Seung-Ki Kwok⁴⁴, Xiaomei Li⁴⁵, Sara S. McCoy⁴⁶, Wan-Fai Ng^{47,48}, Peter Olsson⁴⁹, Maureen Rischmueller⁵⁰, Alain Saraux^{51,52}, R. Hal Scofield^{53,54}, Valéria Valim⁵⁵, Claudio Vitali⁵⁶, Frederick Vivino⁵⁷, Marie Wahren-Herlenius⁵⁸ & Haralampos M. Moutsopoulos⁵⁹ on behalf of the International Task Force on Nomenclature of Sjögren Disease*

Abstract

Nomenclature for the disease widely known as Sjögren syndrome has proven unsatisfactory. Patients have perceived 'syndrome' as indicative of a vague collection of symptoms, prompting the Sjögren's Foundation to abandon the term. Furthermore, the traditional distinction between 'primary' and 'secondary' forms fails to account for the complex interplay between overlapping autoimmune diseases. Following a bibliometric analysis, systematic literature review and a Delphi consensus process with equal involvement of professional and patient representatives, five recommendations are now issued. First, the term 'Sjögren disease' should replace 'Sjögren syndrome'. Second, the acronym 'SjD' should be used as an abbreviation for 'Sjögren disease'. Third, the descriptor 'associated' should be used in lieu of 'secondary' for Sjögren disease occurring in association with a second systemic autoimmune disease for which classification criteria are fulfilled. Fourth, Sjögren disease is the preferred terminology in common parlance and in clinical diagnosis, without differentiation as to primary and associated forms. Fifth, the differentiation between primary and associated Sjögren is recommended for scientific studies to define a homogeneous population. In conclusion,

Sections

Introduction
Methods
Results
Discussion
Conclusions

Sjogrens Updates

First, a patient must either be suspected of having Sjögren's based on the EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) with at least 1 domain being positive OR respond positively to at least one of the following questions about symptoms:

1. Have you had daily, persistent, troublesome dry eyes for more than 3 months?
2. Do you have a recurrent sensation of sand or gravel in the eyes?
3. Do you use tear substitutes more than 3 times a day?
4. Have you had a daily feeling of dry mouth for more than 3 months?
5. Do you frequently drink liquids to aid in swallowing dry food?

Second, a patient is excluded for any of the following:

1. History of head and neck radiation treatment
2. Active hepatitis C infection (with confirmation by polymerase chain reaction), HIV
3. Sarcoidosis
4. Amyloidosis
5. Graft-versus-host disease
6. IgG4-related disease

Finally, a diagnosis of Sjögren's is based on the weighted sum of 5 items. A patient must have a total score of ≥ 4 to meet Classification Criteria for a Sjögren's diagnosis for a clinical trial.

ACR-EULAR 2016 Classification Criteria for Sjögren's

Item #	Item to be Scored	Weight
1	Labial salivary gland with focal lymphocytic sialadenitis and focus score of ≥ 1 foci/4 mm	3
2	Anti-SSA/Ro positive	3
3	Ocular Staining Score ≥ 5 (or van Bijsterveld score ≥ 4) in at least 1 eye	1
4	Schirmer's test ≤ 5 mm/5 minutes in at least 1 eye	1
5	Unstimulated whole saliva flow rate ≤ 0.1 ml/minute	1

ABSTRACT NUMBER: 0513

Real-world Clinical and Diagnostic Features of Patients with Isolated Anti-SSB Antibodies Compared to Those with Combination Anti-SSA and Anti-SSB Antibodies

Massiel Jimenez Artiles¹

Results: A total of 315 patients were included: 109 with isolated anti-SSB and 206 with both anti-SSA/SSB positivity. The groups were similar in age and sex distribution (83% vs. 85% female). Compared to the dual-positive anti-SSA/anti-SSB, patients with isolated anti-SSB antibody were significantly less likely to exhibit anemia, leukopenia, proteinuria, or positive ANA. Other autoantibodies (anti-Smith, anti-RNP, RF, anti-CCP) were also less frequent in the isolated anti-SSB group. Additionally, **this group had lower rates of xerophthalmia and diagnoses of Sjögren’s disease**, systemic lupus erythematosus, and rheumatoid arthritis, and were more often left without a rheumatologic diagnosis.

Conclusion: Isolated anti-SSB positivity is associated with a significantly lower likelihood of Sjögren’s disease, SLE, and RA.

Symptoms	Anti-SSA/SSB	Anti-SSB	p-value
Joint pain	1.5 (0.2 - 12.2)	0.7 (0.1 - 5.7)	0.725
Joint swelling	0.89 (0.1 - 5.3)	1.1 (0.2 - 6.8)	0.896
Joint stiffness	1.2 (0.1 - 10.3)	0.8 (0.1 - 7.0)	0.86
Xerophthalmia	21.5 (2.5 - 185.4)	0.1 (0.0 - 0.4)	0.005
Xerostomia	4.0 (0.7 - 24.1)	0.2 (0.0 - 1.5)	0.126
Hair loss	1.5 (0.2 - 14.8)	0.6 (0.1 - 6.2)	0.705
Skin rash	0.3 (0.1 - 1.7)	3.1 (0.6 - 15.9)	0.181
Serositis	5.1 (0.2 - 116.0)	0.2 (0.0 - 4.5)	0.31

ematologic, Chemistry, Autoantibody, and Immunologic Laboratory Comparison

Diagnosis	Anti-SSA/SSB (n=206)	Anti-SSB (n=109)	p-value
Sjogren’s Disease	134 (65%)	27 (24%)	<0.001
Systemic Lupus Erythematosus	68 (33%)	8 (7%)	<0.001
Rheumatoid arthritis	25 (12%)	2 (2%)	<0.001
Other rheumatologic diagnosis*	27 (13%)	19 (17%)	0.318
No rheumatologic diagnosis	62 (30%)	86 (79%)	<0.001

*Includes: polymyositis, dermatomyositis, undifferentiated connective tissue disease, mixed connective tissue disease, axial spondyloarthritis, or systemic sclerosis.

A cross-sectional observational study of patients with sicca with salivary autoantibodies defines a potential new phenotype of Sjögren's disease

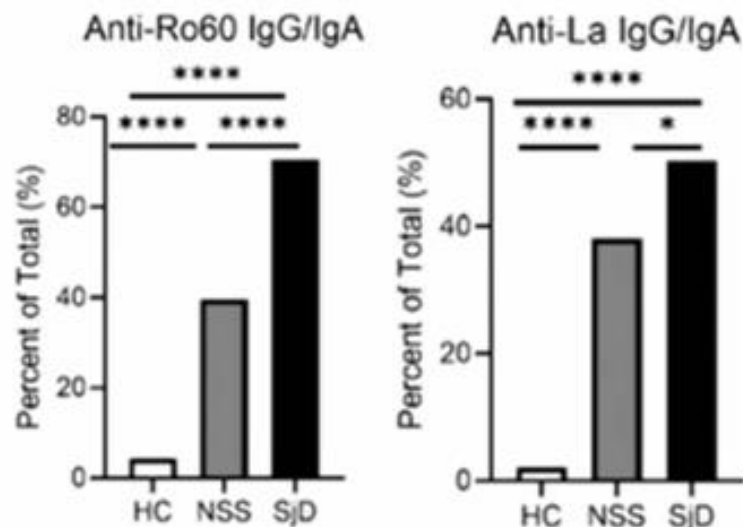
Martha Tsaliki^{1,2,3}, Joshua Cavett^{1,3}, Biji T. Kurien^{1,3}, Christina Bruxvoort^{1,2,3}, Valerie M. Lewis^{1,3}, John A. Ice^{1,3}, Devavrat Dave^{1,4}, Sina Khosravani¹, Kiely Grundahl^{1,5}, Christopher J. Lessard^{2,5}, Astrid Rasmussen⁵, Kathy L. Sivits¹, Amy Darise Farris¹, Kristi A. Koelsch¹, Robert Hal Scofield^{1,3,4,5}

Annals of the Rheumatic Diseases

- N=175 SjD
- N=225 NSS
- N=46 healthy control
- **Salivary** autoantibodies (Ro60, La, RF) by ELISA from WUSF

R-SjD = NSS reclassified to SjD by using salivary Ro60

Salivary autoantibody prevalence



ACR
Convergence

Bryant England, MD, PhD

University of Nebraska Medical Center

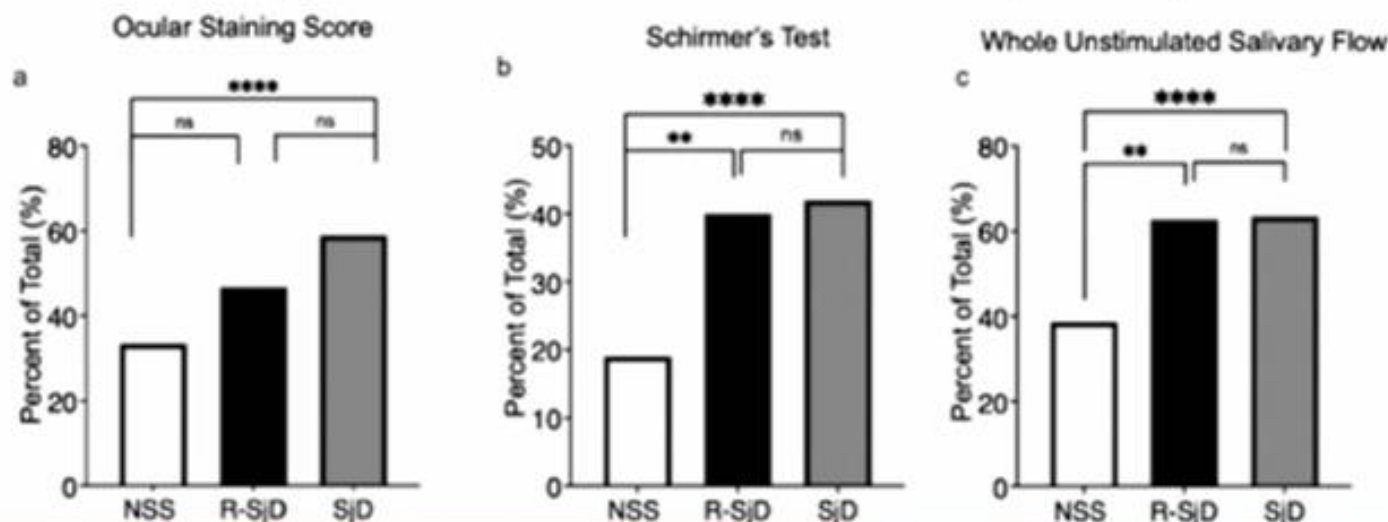
Year in Review: Clinical Science

Sunday, October 26, 2025

75/88 NSS with salivary Ro60 reclassified as SjD

Most with negative Focus score

Dryness measures similar between R-SjD and SjD

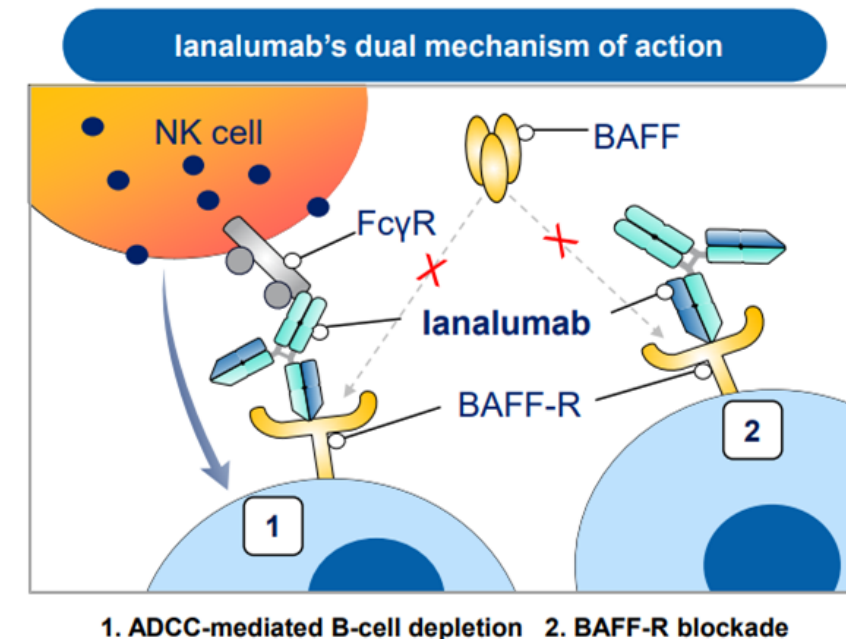


Ianalumab demonstrates significant reduction in disease activity in patients with Sjögren's disease: Efficacy and safety results from two global Phase 3, randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2).

Thomas Grader-Beck

Sjögren's disease: High unmet need without approved systemic treatments

- **Sjögren's disease** (SjD) is a heterogeneous, systemic autoimmune disease with a **substantial disease burden**¹
- **B cell hyperactivity** and **dysregulated BAFF/BAFF-R signalling** are a hallmark of SjD pathogenesis²⁻⁴
- **Ianalumab** is an **afucosylated, fully human, IgG1 mAb** targeting **B cells** through a **novel dual mechanism of action**, by binding to **BAFF-R**:
 - [1] Depletion of B cells through **enhanced ADCC**
 - [2] Inhibition of B cell activation and survival via **BAFF-R blockade**^{4,5}
- Ianalumab showed **preliminary efficacy and a favorable safety profile** in patients with SjD (Phase 2b) and SLE (Phase 2)^{6,7}



Oral presentation: LB24
Date and time: October 29 2025, 9:15 AM – 9:30 AM
Session: (LB19-LB24) Late-Breaking Abstracts

Thomas Grader-Beck
tgrader1@hms.edu

Ianalumab demonstrates significant reduction in disease activity in patients with Sjögren's Disease: Efficacy and safety results from two global Phase 3, randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2)



NEPTUNUS-1 (NCT05350072) and NEPTUNUS-2 (NCT05349214) are two replicate Phase 3 studies designed to confirm the **efficacy and safety of Ianalumab** in patients with active SjD

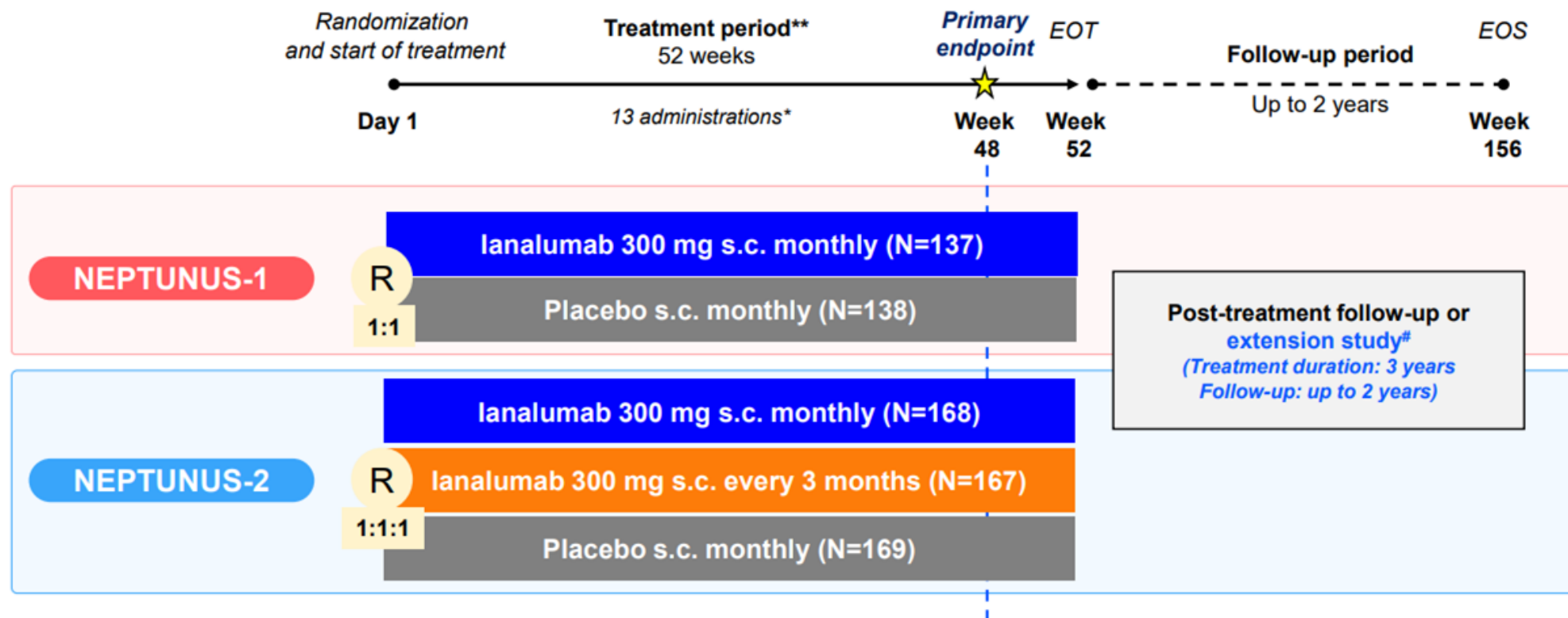
Thomas Grader-Beck*, Xavier Mariette*, Stephanie Finzel, Elena Schiopu, Athena Papas, Valerie Devauchelle-Pensec, Thomas Dörner, Monika Sopala, Xiaofeng Zeng, Ghaith Noaiseh, Tsutomu Takeuchi, Uma Kumar, Josef Hermann, Hiroki Ozawa, Robert Fox, Susan Zong, Deepak Narayanswamy, Xiaomei Li, Wen-Lin Luo, Janice Woznicki, Laurie Debonnett, Xuan Zhu, Linchen He, Franziska Matzkies, Angelika Jahreis, Brian Porter, Sara McCoy, Simon J. Bowman, Wolfgang Hueber



Scan to download a copy of this presentation
<https://www.medicinesonline.com/abstracts/abstract/2580>
Copies of this poster displayed through Open Access (OA) code are for personal use only and may not be reproduced without the permission of the authors.

ADCC, antibody-dependent cellular cytotoxicity; BAFF, B cell-activating factor; BAFF-R, BAFF receptor; mAb, monoclonal antibody; NK, natural killer; SjD, Sjögren's disease; SLE, systemic lupus erythematosus.
1. Pelkas C, et al. *Best Pract Res Clin Rheumatol*. 2025;102084; 2. Mariette X, et al. *Ann Rheum Dis*. 2003;62(2):168-71; 3. Perosa F, et al. *J Int Med*. 2010;267:260-277; 4. Nocturne G, et al. *Nat Rev Rheumatol*. 2018;14(3):133-145; 5. Dörner T, et al. *Ann Rheum Dis*. 2019;78:641-647; 6. Bowman SJ, et al. *Lancet*. 2022;399:161-171. 7. Mysler E, et al. [abstract #2580]. *Arthritis Rheumatol*. 2024; 76 (9).

NEPTUNUS-1 and NEPTUNUS-2 are 52-week, randomized, double-blind, placebo-controlled, 2- and 3-arm Phase 3 studies



Oral presentation: LB24
Date and time: October 29 2025, 9:15 AM – 9:30 AM
Session: (LB19–LB24) Late-Breaking Abstracts

lanalumab demonstrates significant reduction in disease activity in patients with Sjögren's syndrome. Efficacy and safety results from two large randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2)

*Patients in the lanalumab QM arm received monthly administrations of the blinded study treatment, where "monthly" is defined by a 28-day (4-week) interval and patients in the lanalumab Q3M arm received monthly placebo injections between quarterly administrations of lanalumab. **Patients who discontinued the study treatment prior to week 48 could continue study assessments as per the treatment period schedule until Week 52 or directly enter post-treatment follow up period; *Patients who completed the entire treatment up to Week 48 (without treatment discontinuation), could participate in a separate extension study. EOT, end of treatment; EOS, end of study; QM, monthly; Q3M, every 3 months; R, randomization; s.c., subcutaneous.

Thomas Grader-Beck*, Xavier Mariette*, Stephanie Finzel, Elena Schiopu, Athena Papas, Valerie Devauchelle-Pensec, Thomas Dörner, Monika Sopala, Xiaofeng Zeng, Ghaith Noaiseh, Tsutomu Takeuchi, Uma Kumar, Josef Hermann, Hiroki Ozawa, Robert Fox, Susan Zong, Deepak Narayanswamy, Xiaomei Li, Wen-Lin Luo, Janice Woznicki, Laurie Debonnett, Xuan Zhu, Linchen He, Franziska Matzkies, Angelika Jahreis, Brian Porter, Sara McCoy, Simon J. Bowman, Wolfgang Hueber



Patients and study endpoints (NEPTUNUS-1 and NEPTUNUS-2)

Key inclusion criteria

- Adult patients fulfilling the ACR/EULAR 2016 classification criteria
- **Time since diagnosis: ≤ 7.5 years**
- **ESSDAI ≥ 5**
- **Stimulated salivary flow (sSF) rate: ≥ 0.05 mL/min**
- **Stable background medication** (MTX ≤ 25 mg/week, HCQ ≤ 400 mg/day, AZA ≤ 150 mg/day, prednisone ≤ 10 mg/day)

Key exclusion criteria

- Other autoimmune rheumatic diseases if active and principal illness
- Active infections
- Use of other investigational drugs
- Prior use of treatment with biologics or immunosuppressants (other than those allowed by the protocol)
- Pregnancy and lactation

Primary endpoint

- **ESSDAI Change from baseline (CFB) at Week 48** (ianalumab compared to placebo)

Key secondary endpoints

- ESSDAI response (≥ 5 points reduction from baseline) at Week 48
- ESSDAI low systemic disease activity (ESSDAI score < 5) at Week 48
- ESSPRI CFB and response at Week 48
- SSSD CFB and response at Week 48
- PhGA, PaGA, and sSF CFB at Week 48
- Safety and tolerability up to Week 52

Pooled analysis

- Pooled analysis of NEPTUNUS-1 and -2 (for ianalumab QM only) was prespecified*

Oral presentation: LB24
Date and time: October 29 2025, 9:15 AM – 9:30 AM
Session: (LB19–LB24) Late-Breaking Abstracts

Ianalumab demonstrates significant reduction in disease activity in patients with Sjögren's Syndrome. Efficacy and safety results from two global randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2)

Thomas Grader-Beck*, Xavier Mariette*, Stephanie Finzel, Elena Schiopu, Athena Papas, Valerie Devauchelle-Pensec, Thomas Dörner, Monika Sopala, Xiaofeng Zeng, Ghaith Noaiseh, Tsutomu Takeuchi, Uma Kumar, Josef Hermann, Hiroki Ozawa, Robert Fox, Susan Zong, Deepak Narayanswamy, Xiaomei Li, Wen-Lin Luo, Janice Woznicki, Laurie Debonnett, Xuan Zhu, Linchen He, Franziska Matzkies, Angelika Jahreis, Brian Porter, Sara McCoy, Simon J. Bowman, Wolfgang Hueber



*Prespecified in the Summary of Clinical Efficacy statistical plan for health authority submission

ACR, American College of Rheumatology; AZA, azathioprine; CFB, change from baseline; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EULAR, European Alliance of Associations for Rheumatology; HCQ, hydroxychloroquine; MTX, methotrexate; PaGA, Patient's Global Assessment; PhGA, Physician's Global Assessment; QM, monthly; sSF, stimulated whole-salivary flow; SSSD, Sjögren's Syndrome Symptom Diary.

American College of Rheumatology | Chicago, Illinois. 24-29 October 2025

Baseline characteristics were generally balanced between treatment groups

Characteristics	NEPTUNUS-1 (N=275)		NEPTUNUS-2 (N=504)		
	lanalumab QM N=137	Placebo N=138	lanalumab QM N=168	lanalumab Q3M N=167	Placebo N=169
Age (years)*	48.8 (11.7)	48.0 (13.8)	49.6 (11.4)	50.4 (12.7)	50.9 (12.8)
<65 years, n (%)	125 (91.2)	126 (91.3)	149 (88.7)	145 (86.8)	143 (84.6)
Female, n (%)	127 (92.7)	127 (92.0)	158 (94.0)	159 (95.2)	161 (95.3)
ESSDAI*	12.7 (6.8)	12.6 (6.7)	11.7 (5.8)	11.5 (6.2)	12.1 (5.7)
ESSDAI >13, n (%)	51 (37.2)	48 (34.8)	52 (31.0)	41 (24.6)	47 (27.8)
ESSPRI*	6.40 (2.0)	6.01 (2.2)	6.29 (2.1)	6.21 (2.2)	6.26 (2.2)
ESSPRI ≥5, n (%)	108 (78.8)	95 (68.8)	126 (75.0)	123 (73.7)	130 (76.9)
sSF (mL/min)*	0.62 (0.6)	0.65 (0.5)	0.62 (0.6)	0.56 (0.7)	0.70 (0.7)
Positive anti-Ro/SSA status, n (%)	125 (91.2)	132 (95.7)	160 (95.2)	161 (96.4)	158 (93.5)
Any DMARD use, n (%)	85 (62.0)	94 (68.1)	109 (64.9)	100 (59.9)	117 (69.2)
HCQ	65 (47.4)	78 (56.5)	95 (56.5)	82 (49.1)	103 (60.9)
MTX	29 (21.2)	22 (15.9)	22 (13.1)	21 (12.6)	26 (15.4)
AZA	4 (2.9)	14 (10.1)	9 (5.4)	14 (8.4)	10 (5.9)
Systemic CS usage, n (%)	43 (31.4)	47 (34.1)	43 (25.6)	42 (25.1)	44 (26.0)
≥5 mg/day	35 (25.5)	40 (29.0)	40 (23.8)	39 (23.4)	33 (19.5)

*Values are presented as mean (SD), unless otherwise specified.

Ro/SSA, anti-Ro/Sjögren's Syndrome A; AZA, azathioprine; CS, corticosteroids; DMARD, disease-modifying antirheumatic drug; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; EULAR, European Alliance of Associations for Rheumatology; HCQ, hydroxychloroquine; MTX, methotrexate; QM, monthly; Q3M, every 3 months; SD, standard deviation; sSF, stimulated whole-salivary flow.

Oral presentation: LB24
Date and time: October 29 2025, 9:15 AM - 9:30 AM
Session: (LB19-LB24) Late-Breaking Abstracts

Thomas Grader-Beck
Larad1.LB24.001

lanalumab demonstrates significant reduction in disease activity in patients with Sjögren's Disease: Efficacy and safety results from two global Phase 3, randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2)

Thomas Grader-Beck*, Xavier Mariette*, Stephanie Finzel, Elena Schiopu, Athena Papas, Valerie Devauchelle-Pensec, Thomas Dörner, Monika Sopaia, Xiaofeng Zeng, Ghath Noaiseh, Tautomu Takeuchi, Uma Kumar, Josef Hermann, Hiroki Ozawa, Robert Fox, Susan Zeng, Deepak Narayanswamy, Xiaomei Li, Wen-Lin Luo, Janice Woznicki, Laurie Debonnett, Xuan Zhu, Linchen He, Franziska Matzies, Angelika Jahreis, Brian Porter, Sara McCoy, Simon J. Bowman, Wolfgang Hueber

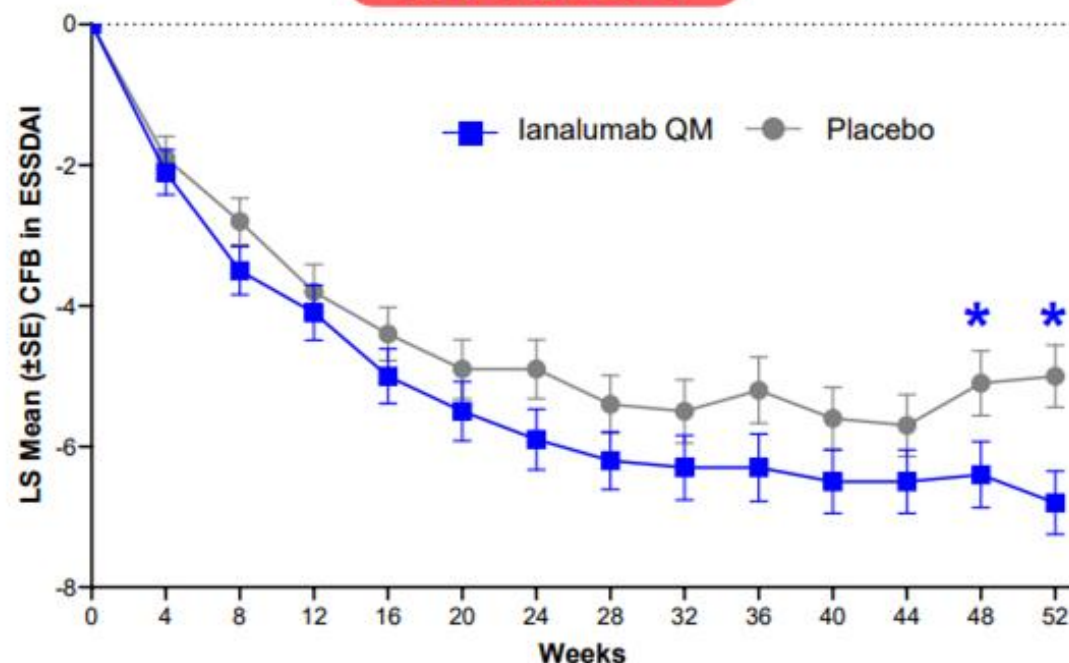


Scan to download
a copy of this
presentation
<https://onlinelibrary.wiley.com/doi/10.1111/1365-3113.12800>
This document is a pre-proof
of the manuscript. It is not
for distribution and should not
be used for any purpose other
than the preparation of the article.

The primary objective was met in both NEPTUNUS-1 and NEPTUNUS-2

Ianalumab 300 mg monthly demonstrated statistically significant improvement in ESSDAI change from baseline at Week 48 compared with placebo in both studies

NEPTUNUS-1

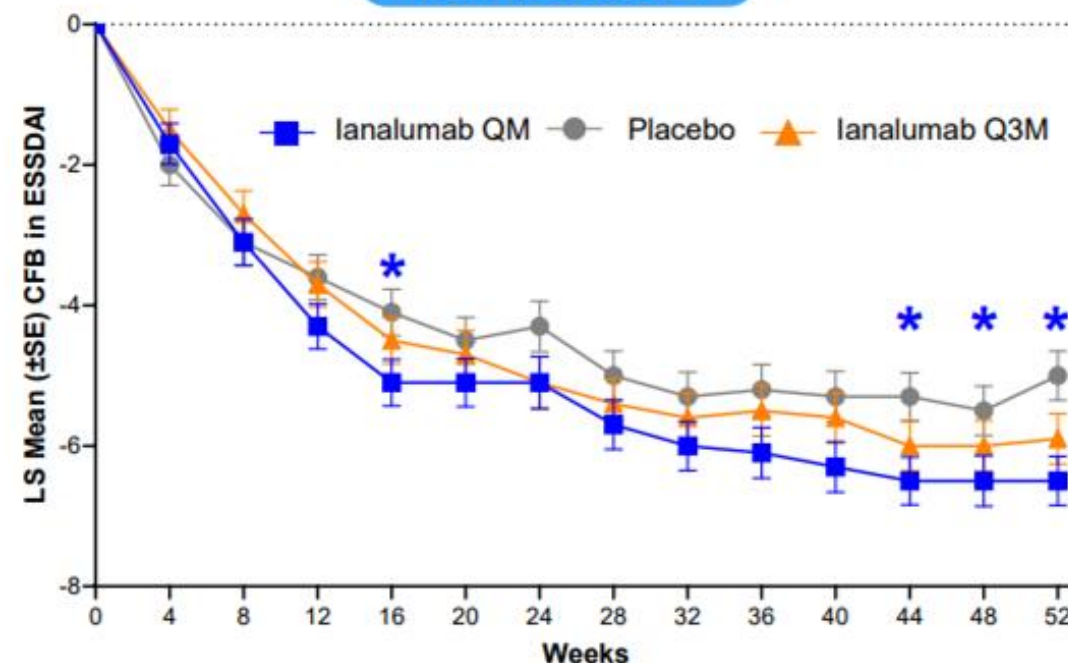


CFB in ESSDAI at Week 48**

Treatment	LS mean (SE)	Δ LS mean (SE)	95% CI	p-value
Ianalumab QM (N=137)	-6.4 (0.47)	-1.3 (0.66)	(-2.6, 0.0)	0.0496
Placebo (N=138)	-5.1 (0.46)			

- Only the primary endpoint was statistically significant in the predefined hypothesis testing hierarchy in both studies

NEPTUNUS-2



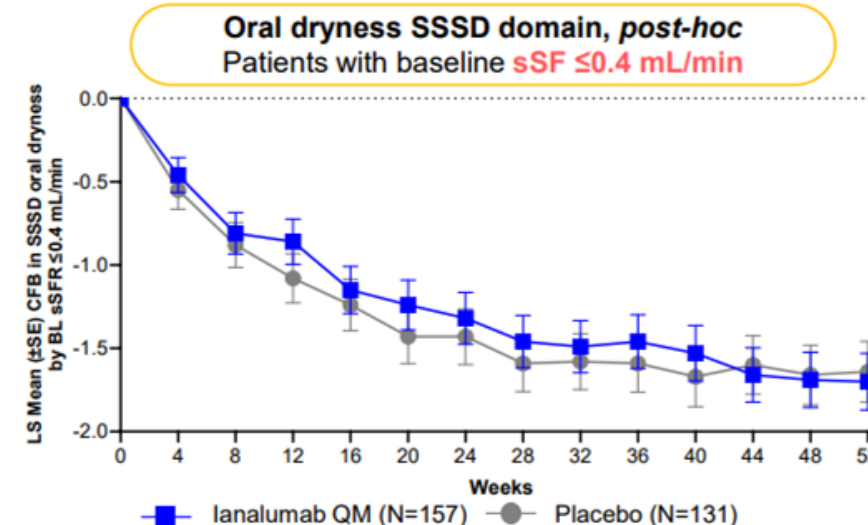
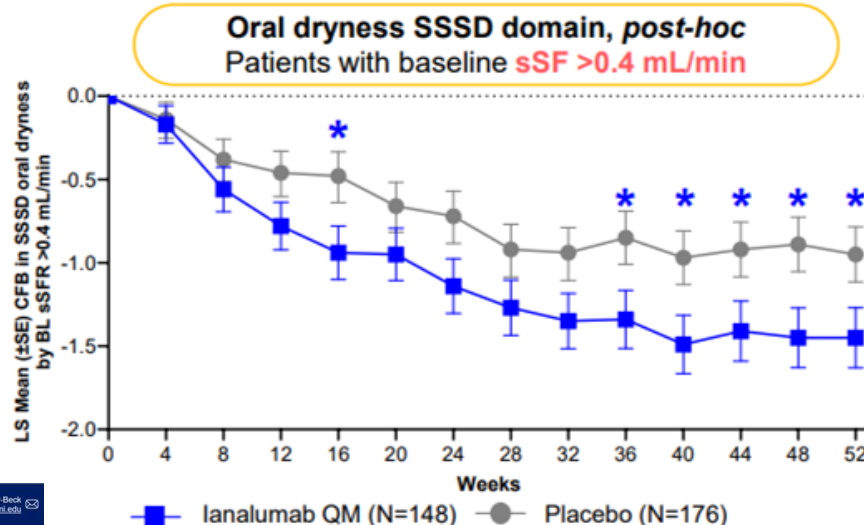
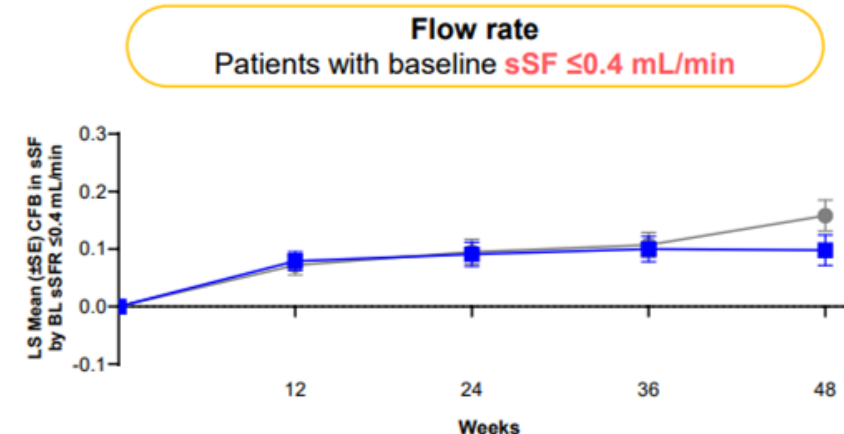
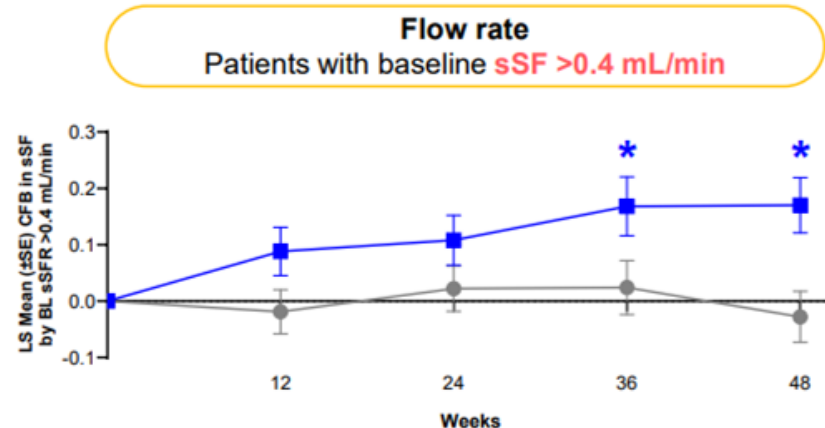
CFB in ESSDAI at Week 48**

Treatment	LS mean (SE)	Δ LS mean (SE)	95% CI	p-value
Ianalumab QM (N=168)	-6.5 (0.36)	-1.0 (0.51)	(-2.0, 0.0)	0.041
Ianalumab Q3M (N=167)	-6.0 (0.36)	-0.5 (0.51)	(-1.5, 0.5)	0.3413
Placebo (N=169)	-5.5 (0.35)			

*p<0.05. **ANCOVA model with study treatment, actual ESSDAI score stratum, and region as factors and baseline score as a covariate

ANCOVA, analysis of covariance; BL, baseline; CFB, change from baseline; CI, confidence interval; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; LS, least squares; N, number of patients in each treatment group of the specified analysis set; n, number of patients with evaluable data; QM, monthly; Q3M, every 3 months; SE, standard error.

Patients with baseline stimulated Salivary Flow rate (sSF) >0.4 mL/min[#] showed greater improvements in sSF with ionalumab 300 mg monthly vs placebo*



Oral presentation: LB24
Date and time: October 29 2023, 9:15 AM - 9:30 AM
Session: (LB19-LB24) Late-Breaking Abstracts

Thomas Grader-Beck
tgrader1@hmc.edu

Ionalumab demonstrates significant reduction in disease activity in patients with Sjögren's Disease: Efficacy and safety results from two global Phase 3, randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2)

ates a significant treatment effect observed with a nominal p -value of <0.05; [#][0.4 mL/min is the median of pooled sSF rate at BL] baseline; sSF, stimulated whole-salivary flow; SSSD, Sjögren's Syndrome Symptom Diary.

Thomas Grader-Beck*, Xavier Mariette*, Stephanie Finzel, Elena Schiopu, Athena Papas, Valerie Devauchelle-Pensec, Thomas Dörner, Monika Sopala, Xiaofeng Zeng, Ghailh Noaiseh, Tautomu Takeuchi, Uma Kumar, Josef Hermann, Hiroki Ozawa, Robert Fox, Susan Zong, Deepak Narayanswamy, Xiaomei Li, Wen-Lin Luo, Janice Woznicki, Laurie Debonnett, Xuan Zhu, Linchen He, Franziska Matzies, Angelika Jahreis, Brian Porter, Sara McCoy, Simon J. Bowman, Wolfgang Hueber



Scan to download a copy of this presentation
https://www.medrxiv.org/content/10.1101/2023.10.29.23290000v1
This content represents the authors' original research. It is not yet certified by peer review and should not be used to guide clinical practice.

Summary and conclusion

- **NEPTUNUS-1** and **NEPTUNUS-2** are the first global replicate Phase 3 studies in **SjD** to meet their primary objective, showing a **statistically significant improvement** in ESSDAI
- **Ianalumab 300 mg monthly improved both physician-assessed and patient-reported outcomes:**
 - Consistent improvements in secondary outcome measures:
 - More patients with **ESSDAI low disease activity**
 - Improvement in **Physician Global Assessment**
 - Reduction in the overall disease burden as assessed by **Patient Global Assessment**
 - **sSF and SSSD oral dryness improved** with ianalumab vs placebo in patients with **sSF>0.4 mL/min at baseline**
 - Numerical improvements in **SSSD** and **ESSPRI**
- **Ianalumab 300 mg monthly** demonstrated a **favorable safety profile**, resulting in a **positive benefit–risk profile** for the treatment of SjD
- In conclusion, **ianalumab provided a clinically meaningful benefit to patients**, as evidenced by **significant improvements in disease activity and reductions in patient burden**



2026 Rheumatology Updates



Thank you!

CME Information

Bartlett Regional Hospital is accredited by the Washington State Medical Association to provide continuing medical education for physicians.

Bartlett Regional Hospital designates this live internet course material for a maximum of 1.0 AMA PRA Category 1 Credit(s)[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclosure of Relevant Financial Relationships:

The planners, faculty and reviewers for this activity have no relevant relationships with ineligible companies to disclose, unless listed below.

All relevant financial relationships have been mitigated to assure no bias is present according to ACCME requirements.

Disclosure of Commercial Support:

There is no commercial support for this activity.

To claim your CME please complete the Survey evaluation from BRHQuestions? Contact BRH Medical Staff Services at:

DepartmentCredentialing@bartlettshospital.org