



EULAR Highlights 2021

Spondyloarthritis

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Imaging in axial spondyloarthritis: what is new?



Data-driven Definitions Based on Inflammatory Lesions for a Positive MRI of the Spine Consistent with Axial Spondyloarthritis

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On behalf of ASAS MRIImagine



OBJECTIVES: What defines a positive MRI for active lesions in the spine indicative of axSpA?





We aimed to identify quantitative cut-offs based on numbers of vertebral corners that define ASASMRIspine+, there being two gold standards:

- A. majority central reader decision as to the presence of spine MRI findings consistent with axSpA
- B. rheumatologist expert opinion diagnosis of axSpA.

CONCLUSIONS

- **Data driven cut-offs based on active lesions for defining a positive MRI of the spine consistent with axSpA are:**
 - **BME in ≥ 4 vertebral corners**
 - Or
 - **BME in ≥ 3 vertebral corners in the setting of additional inflammatory lesions at other locations or the presence of corner fat**

Data-driven definitions for active and structural MRI lesions in the sacroiliac joint in spondyloarthritis and their predictive utility

Walter P. Maksymowych ^{1,2}, Robert G. Lambert^{3,4}, Xenofon Baraliakos⁵, Ulrich Weber^{6,7}, Pedro M. Machado ^{8,9,10}, Susanne J. Pedersen¹¹, Manouk de Hooge^{12,13}, Joachim Sieper¹⁴, Stephanie Wichuk¹, Denis Poddubnyy ¹⁴, Martin Rudwaleit^{15,16}, Désirée van der Heijde¹⁷, Robert Landewe^{18,19}, Iris Eshed ²⁰ and Mikkel Ostergaard^{11,21}

Objective: Identify optimal MRI SIJ lesion cut-offs that reflect definitive active or structural MRI lesions typical of axSpA, or an ASAS positive MRI highly suggestive for axSpA.

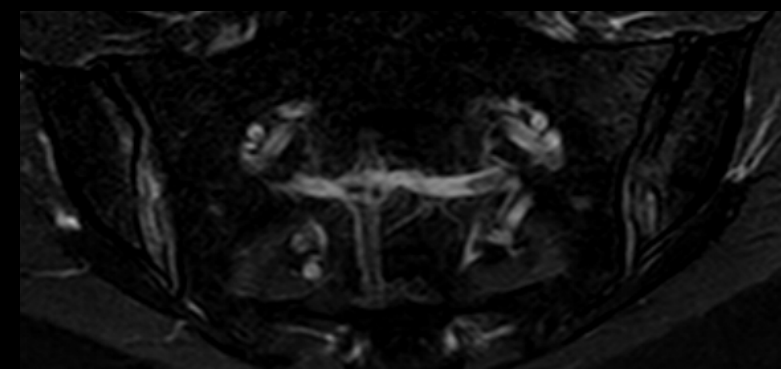
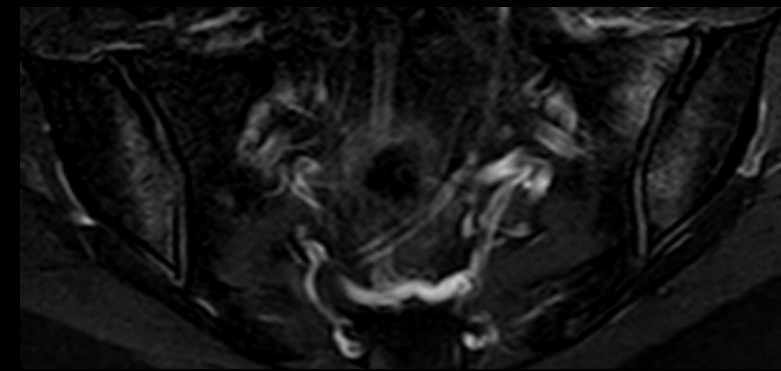
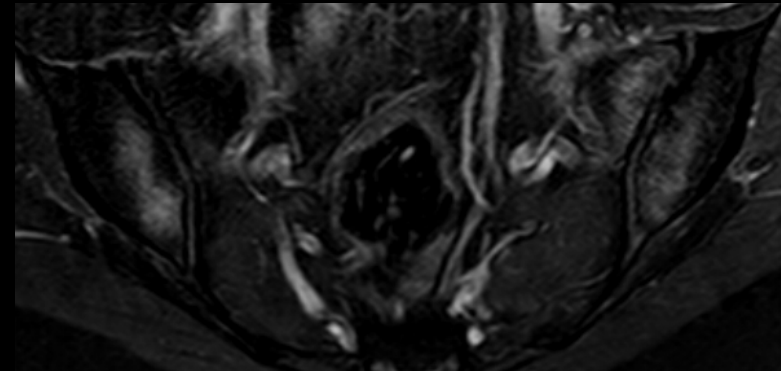
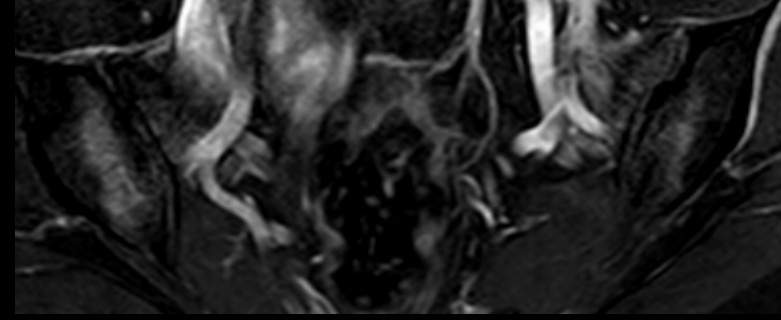
- Bone marrow edema in ≥ 4 SIJ quadrants or in ≥ 3 consecutive slices
- Erosion in ≥ 3 SIJ quadrants or ≥ 2 consecutive slices
- Fat lesions in ≥ 5 SI joint quadrants or ≥ 3 consecutive slices

35-j. Frau mit Beginn von
Lumbosakralgien während
Schwangerschaft.

MRI 3 Monate nach Entbindung
von Zwillingen

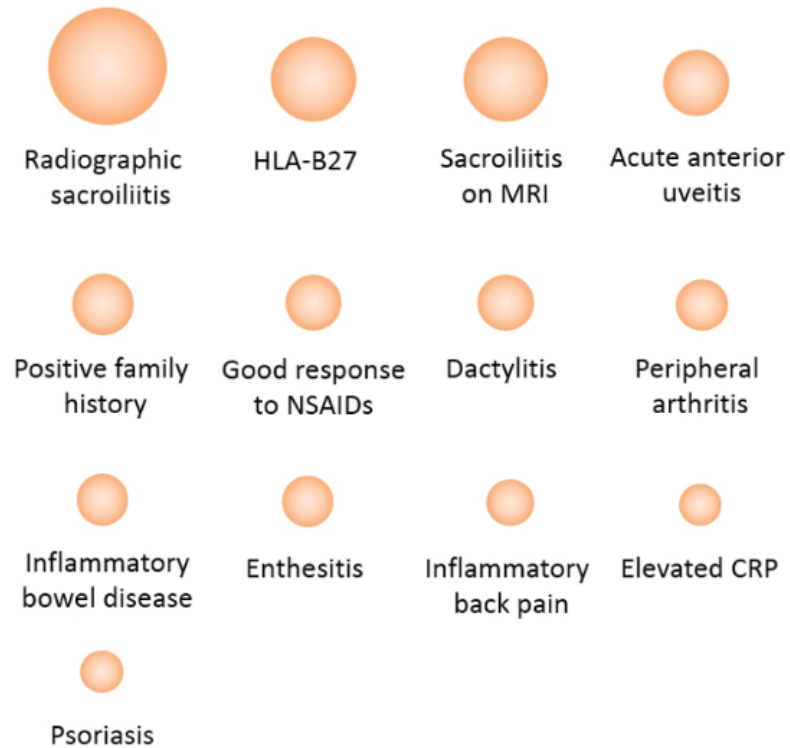
Zu diesem Zeitpunkt (vor 8 Jahren)
Diagnose einer axSpA

Knochenmarködem
angrenzend an mindestens
7 ISG-Quadranten, sichtbar
auf mindestens 4 Schichten

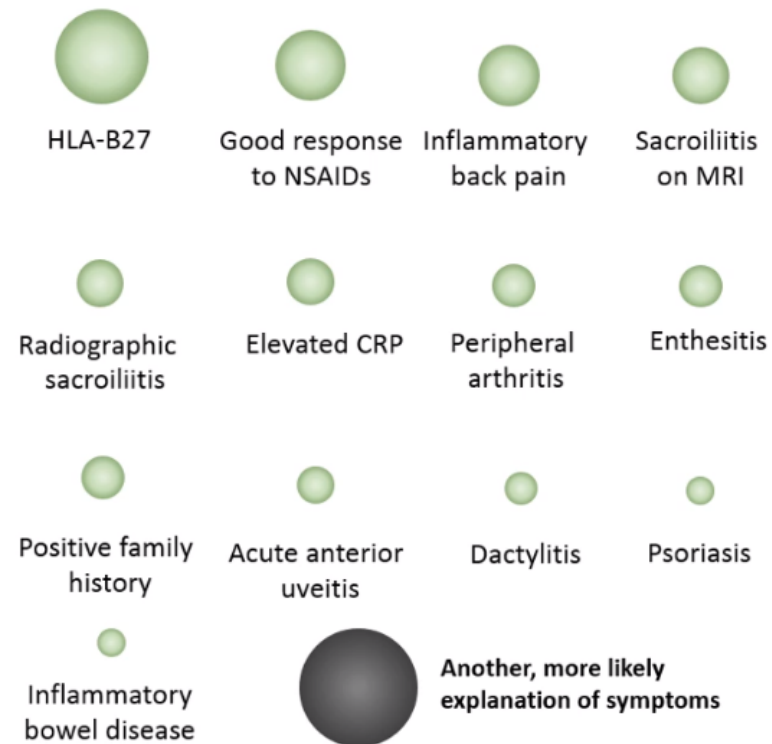


The Diagnostic Weights

Weights of positive test results



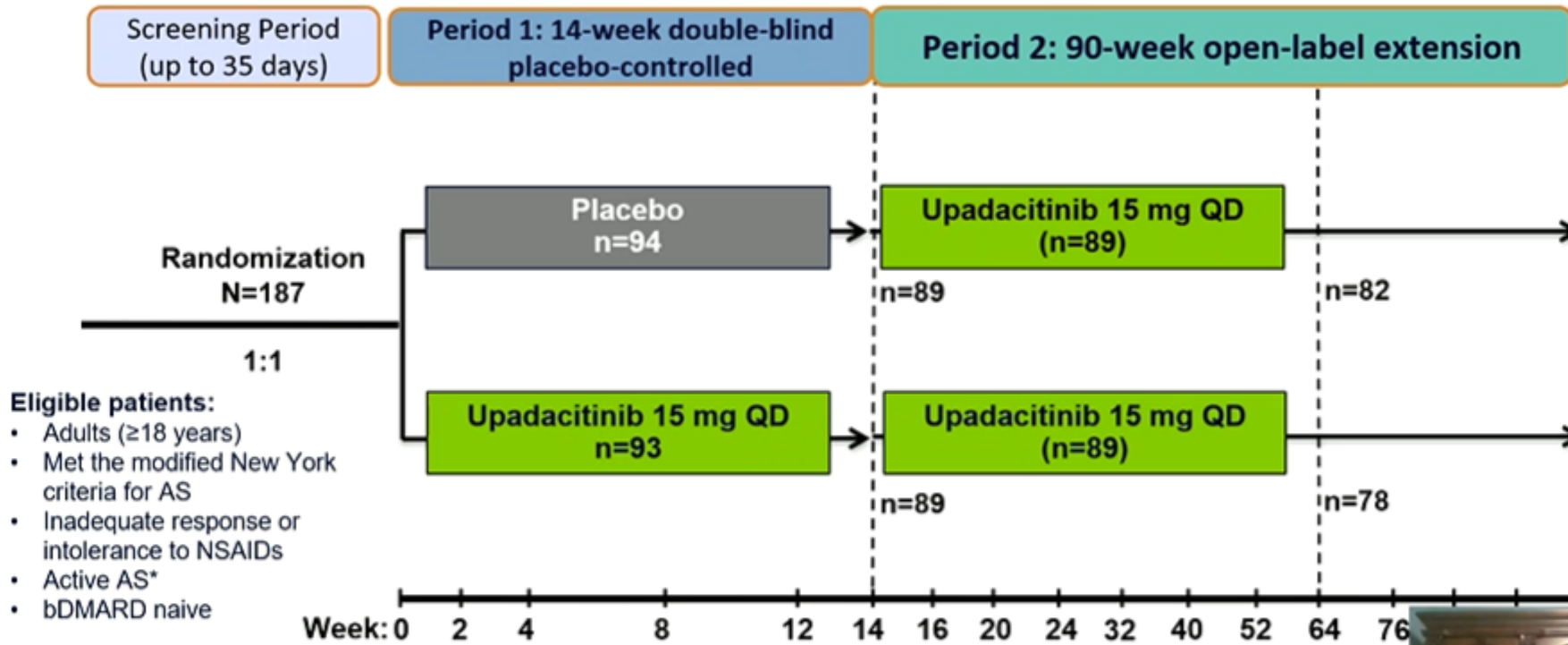
Weights of negative test results



Efficacy and Safety of Upadacitinib in Patients With Active Ankylosing Spondylitis: 1-Year Results From a Randomized, Double-blind, Placebo-controlled Study With Open-label Extension

EULAR 2021 OP0251

Study Design and Participants



- Eligible patients:**
- Adults (≥18 years)
 - Met the modified New York criteria for AS
 - Inadequate response or intolerance to NSAIDs
 - Active AS*
 - bDMARD naive

*BASDAI ≥4 and patient assessment of back pain ≥4 (numeric rating scale, 0–10) at screening and baseline.

Primary endpoint: ASAS40

Interim analysis at week 64

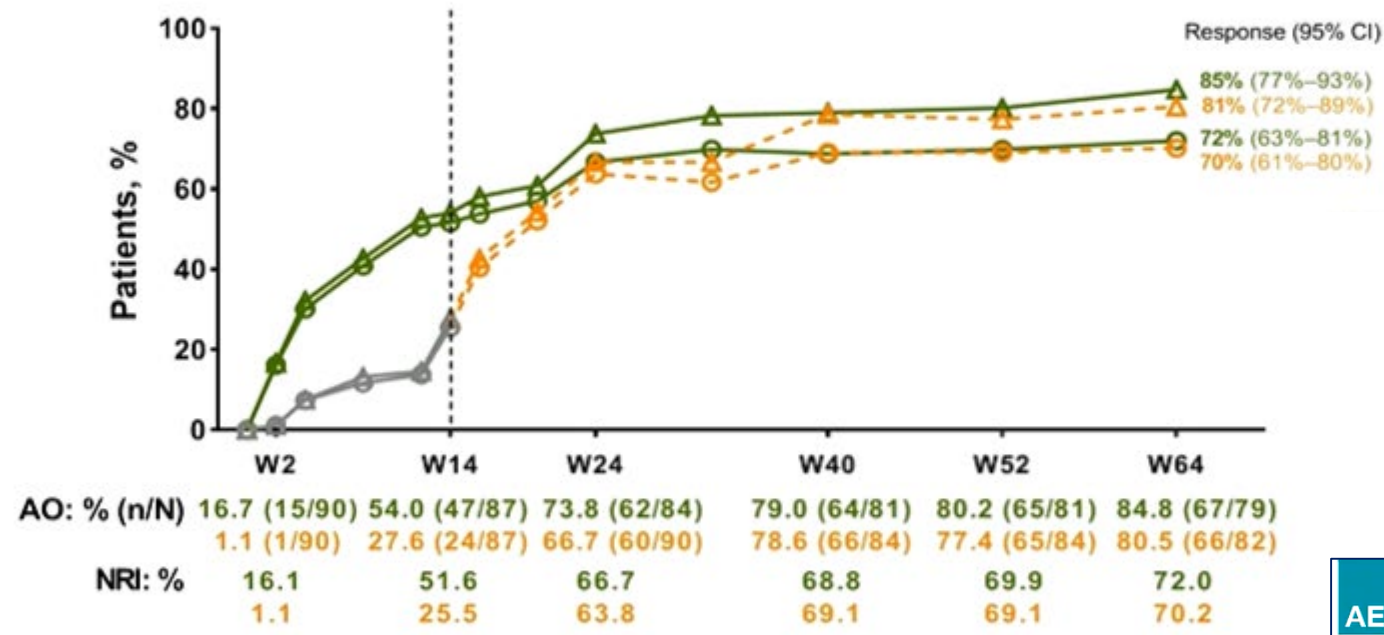
Period 1 data published previously (van der Heijde D, et al. *Lancet*. 2019;394(10214):2108-2117).



Efficacy Through Year 1: ASAS40

EULAR 2021 OP0251

ASAS40



- ▲ Continuous upadacitinib 15 mg QD (AO)
- Continuous upadacitinib 15 mg QD (NRI)
- ▲ Placebo → ▲ Upadacitinib 15 mg QD (AO)
- Placebo → ● Upadacitinib 15 mg QD (NRI)

AE, E (E/100 PY)	Upadacitinib 15 mg QD N = 182 (237.6 PY)
Any AE	618 (260.1)
Serious AE	14 (5.9)
AE leading to discontinuation	15 (6.3)
Infections	205 (86.3)
Opportunistic infection	2 (0.8)
Herpes zoster*	5 (2.1)
Creatine phosphokinase elevation [†]	28 (11.8)
Hepatic disorder [†]	24 (10.1)
Neutropenia	7 (2.9)
Anemia	3 (1.3)
Lymphopenia	2 (0.8)
Malignancy [§]	1 (0.4)
Death	0

Dashed line: all patients randomized to placebo received open-label upadacitinib starting from week 14. NRI analysis: placebo to upadacitinib, n=93. AO, as-observed; ASAS, Assessment of SpondyloArthritis international Society; NRI, non-responder imputation

Effects of filgotinib on spinal lesions in ankylosing spondylitis: Magnetic resonance imaging data from the TORTUGA trial



EULAR 2021 OP0141

The CANDEN MRI spine scoring system allows comprehensive semi-quantitative assessment of inflammation, fat, erosion, and new bone formation of the spine by anatomical location^{3,4}

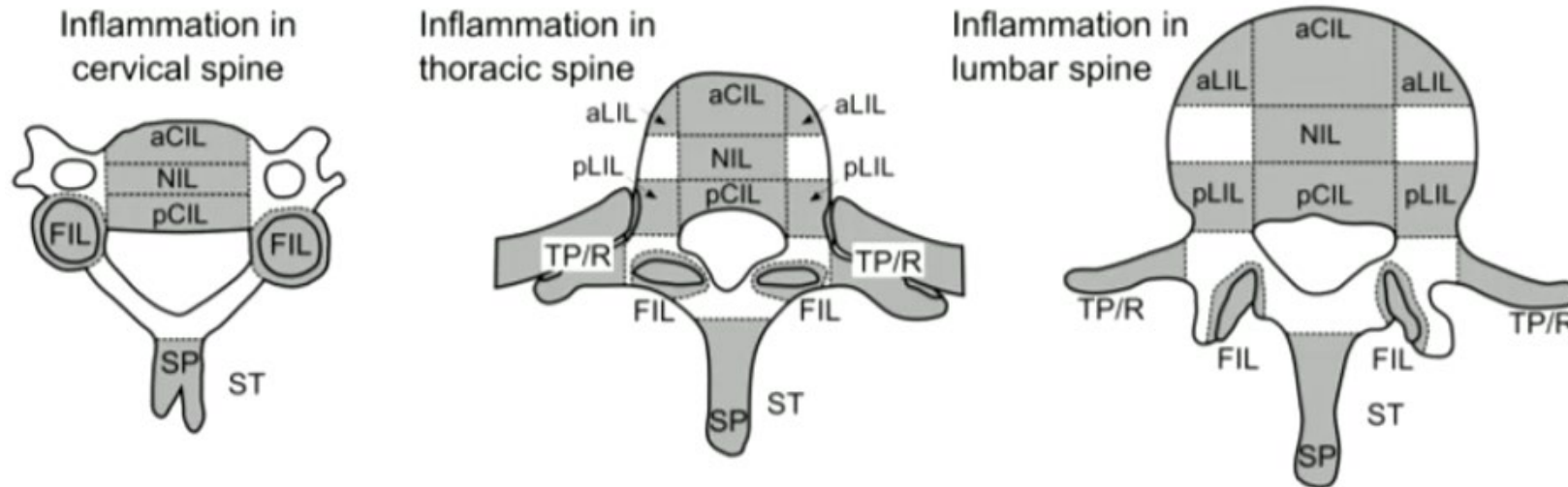
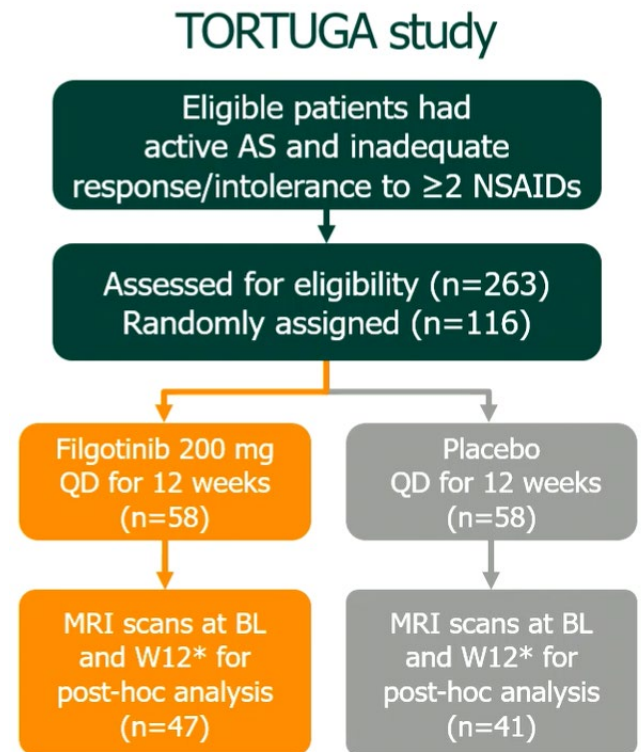
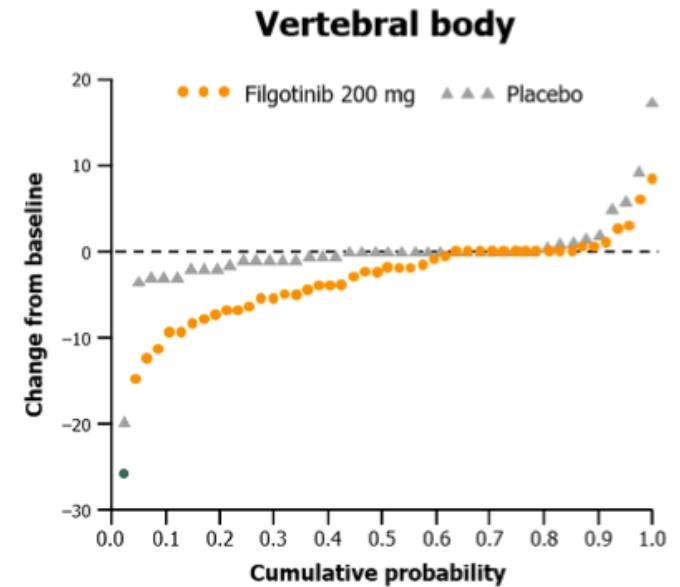
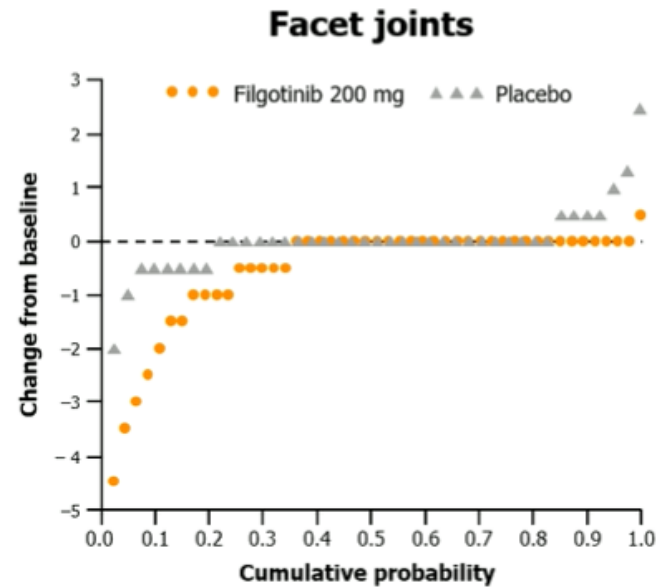
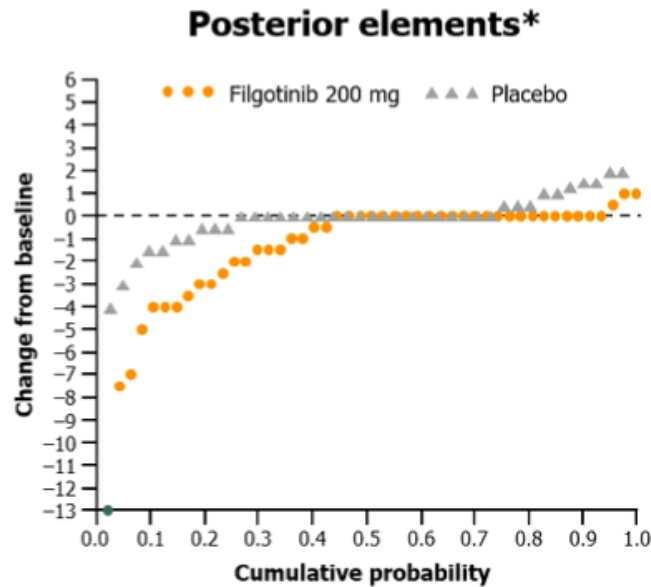
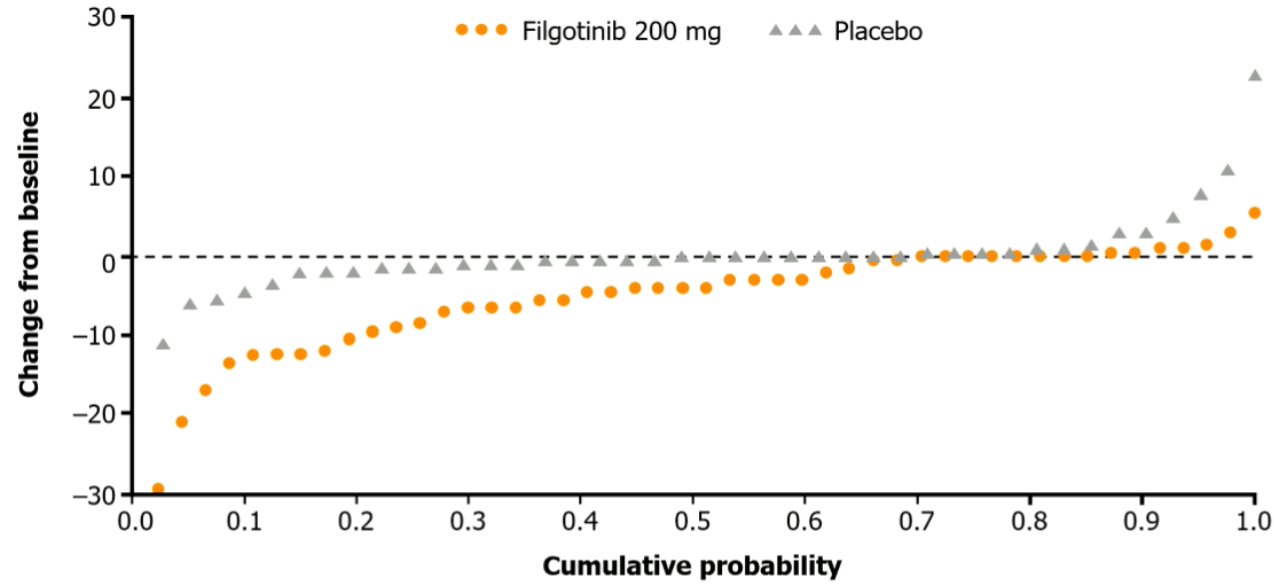


Figure 1b from Krabbe S, et al. RMD Open 2018;4:e000624 reproduced under CC BY-NC 4.0 license



Change from baseline in total CANDEN spine inflammation score

EULAR 2021 OP0141



GRAPPA Treatment Recommendations: 2021 Update

Evidence table

EULAR 2021 OP0229

Patient agreement 87.5%
Clinician agreement 93.8%

Indication	Strong recommendation For	Conditional recommendation For	Conditional recommendation Against	Strong recommendation Against	No recommendation: Insufficient evidence
Peripheral Arthritis DMARD Naïve	csDMARDs, TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i,	NSAIDs, oral CS, IA CS,			
Peripheral Arthritis DMARD IR	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi	PDE4i, other csDMARD, NSAIDs, oral CS, IA CS, CTLA-4-Ig			
Peripheral Arthritis Biologic IR	TNFi, IL-17i, IL-23i, JAKi,	NSAIDs, oral CS, IA CS, IL-12/23i, PDE4i, CTLA-4-Ig			
Axial arthritis, Biologic naïve	NSAIDs, Physiotherapy, simple analgesia, TNFi, IL-17i, JAKi	CS SIJ injections, bisphosphonates		csDMARDs	IL-12/23i, IL-23i
Axial PsA, Biologic IR	NSAIDs, Physiotherapy, simple analgesia, TNFi, IL-17i, JAKi			csDMARDs	IL-12/23i, IL-23i

GRAPPA Treatment Recommendations: 2021 Update

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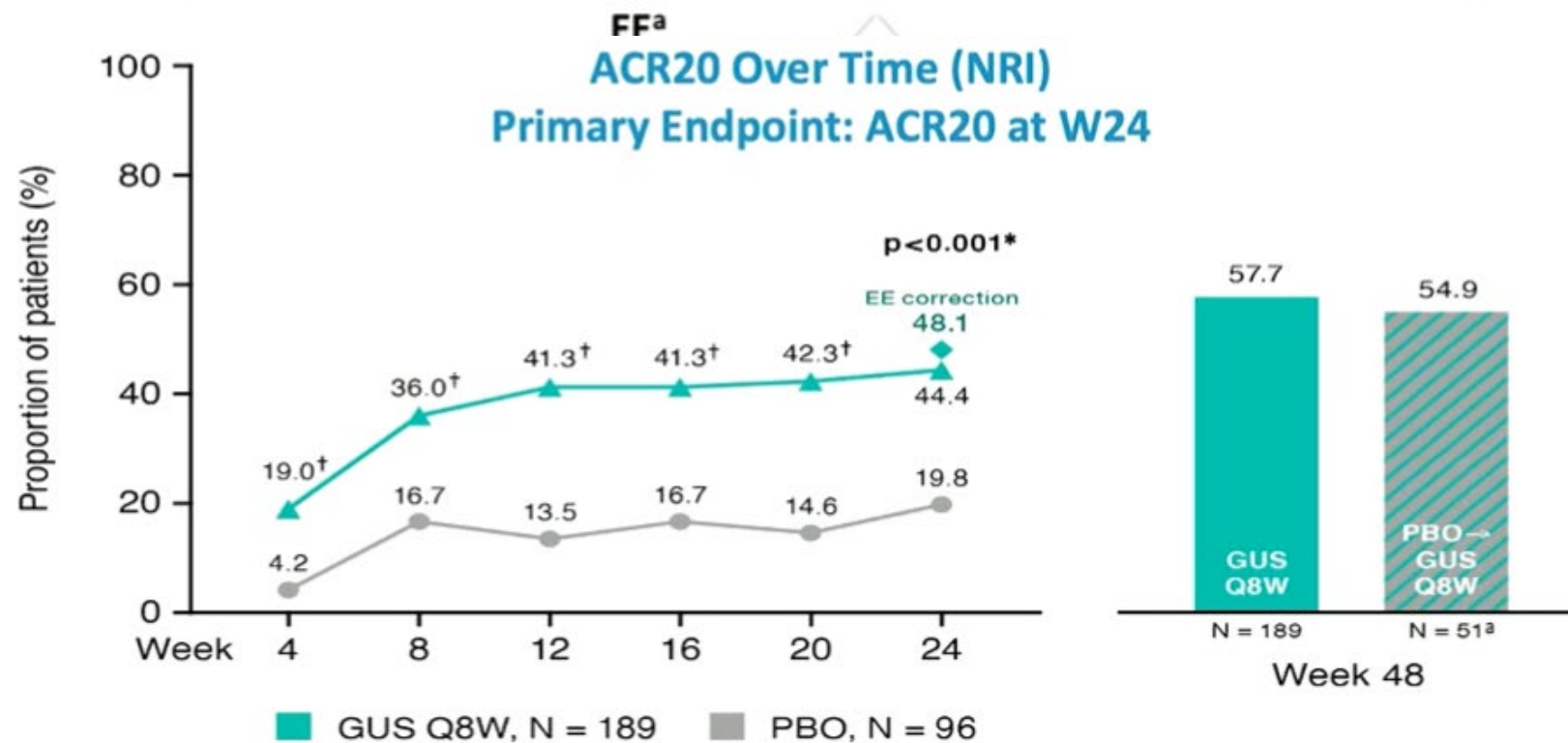
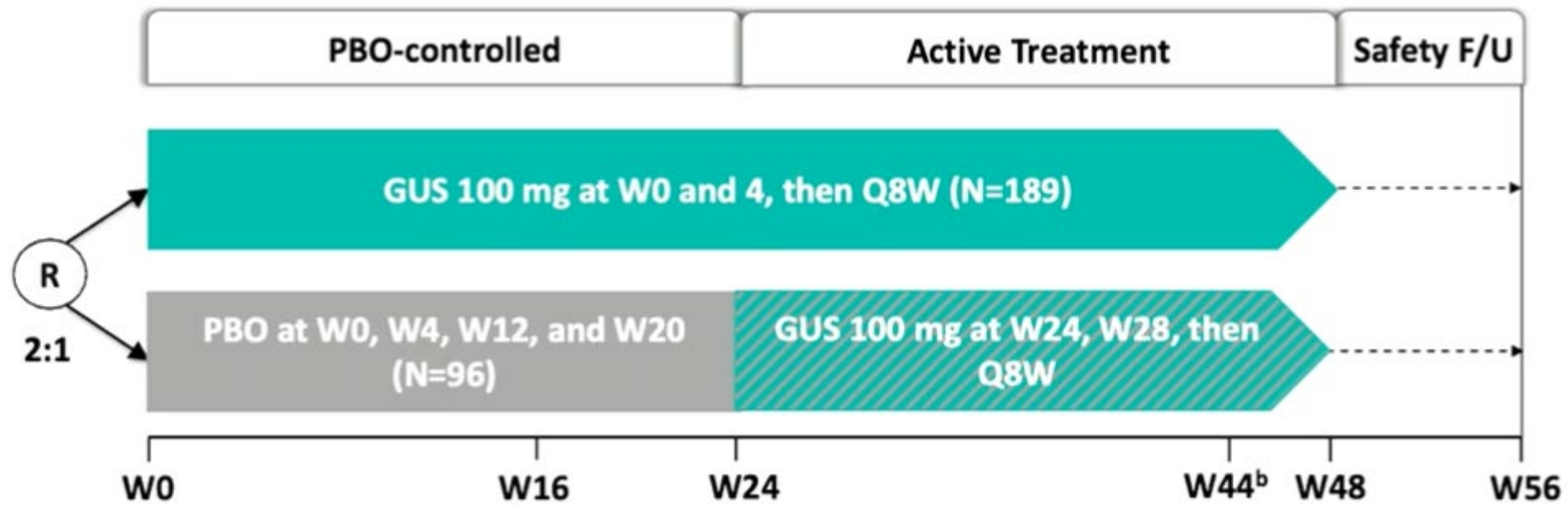
Indication	Strong recommendation For	Conditional recommendation For	Conditional recommendation Against	Strong recommendation Against	No recommendation: Insufficient evidence
Enthesitis	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	NSAIDs, physiotherapy, MTX, CTLA-4-Ig, CS injections (with extreme caution),			Other csDMARDs
Dactylitis	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	NSAIDs, CS injections, MTX, CTLA-4-Ig,	Other csDMARDs		
Psoriasis (plaque)	Topical therapies, phototherapy, Conventional systemics (MTX, fumarates, CyA) TNFi, IL-12/23i, IL-17i, IL-23i, PDE4i, JAKi	Acitretin			
Nail psoriasis	TNFi, IL12/23i, IL17i, IL23i, PDE4i	Topical corticosteroids, tacrolimus and calcipotriol combination or individual therapies, Pulsed dye laser, csDMARDs, acitretin, JAKi			Topical CyA / T F U F A



Efficacy and Safety of Guselkumab in Patients With Active Psoriatic Arthritis who Demonstrated Inadequate Response to Tumor Necrosis Factor Inhibition: Results of a Phase 3b, Randomized, Controlled Study

EULAR 2021 OP0230

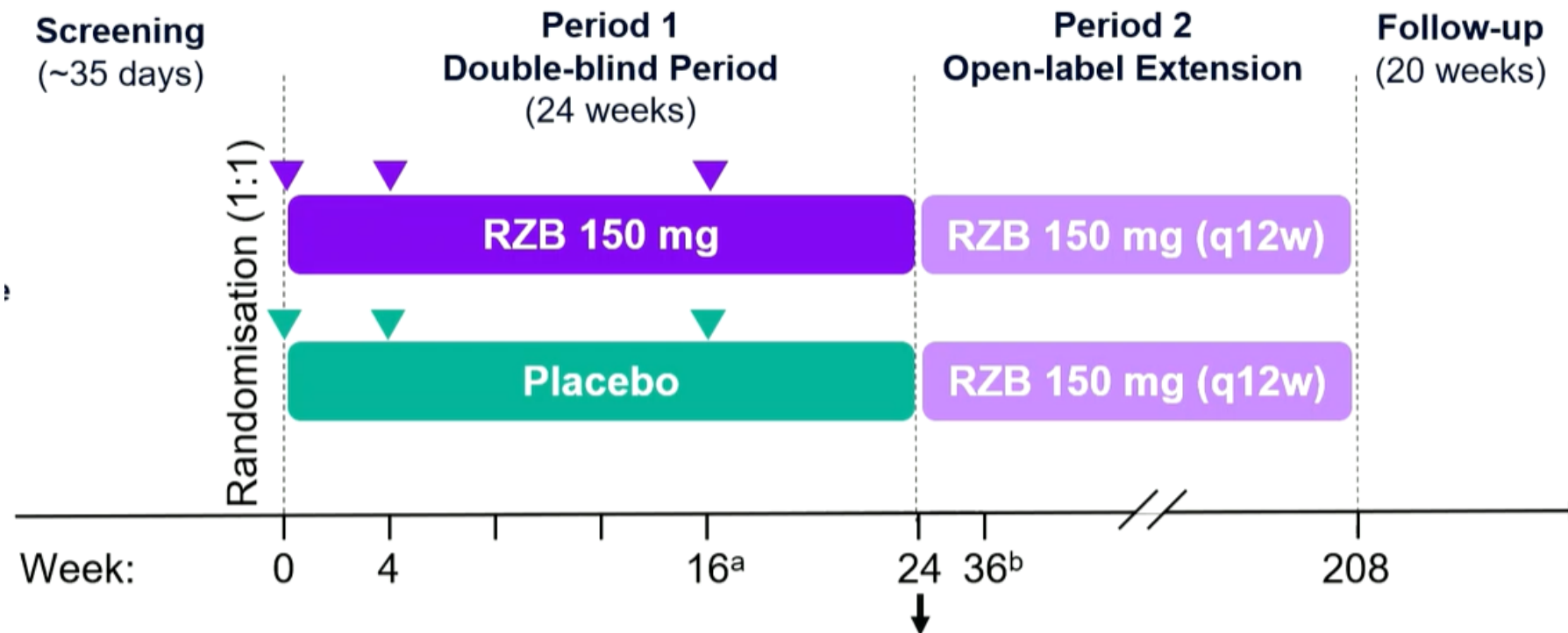
- Guselkumab (GUS), a selective monoclonal antibody targeting the interleukin-23 p19 subunit, is approved to treat adults with moderate-to-severe plaque psoriasis (PsO) and active psoriatic arthritis (PsA)
- In 2 Phase 3 PsA studies, DISCOVER-1¹ and DISCOVER-2,² significantly higher proportions of GUS- than placebo (PBO)-treated patients (pts) achieved joint and skin responses at Week (W) 24. In DISCOVER-1, GUS efficacy was consistent in a subgroup of tumor necrosis factor inhibitor (TNFi)-experienced pts,¹ a cohort of PsA pts with significant unmet needs.
- Here we report GUS efficacy and safety in PsA pts with inadequate response (IR) to 1-2 TNFi assessed in the Phase 3b COSMOS study



Efficacy and Safety of Risankizumab for Active Psoriatic Arthritis, Including Patients With Inadequate Response or Intolerance to Biologic Therapies: 24-Week Results From the Phase 3, Randomized, Double-blind, **KEEPsAKE 2** Trial

EULAR 2021 OP0228

- Risankizumab (RZB), is a humanized immunoglobulin G1 monoclonal antibody that binds to p19 subunit of IL-23 and selectively inhibits this cytokine.^{2,3} RZB is approved for the treatment of moderate-to-severe plaque psoriasis in adults



Characteristic	RZB 150 mg N = 224	PBO N = 219
Prior biologics (any), n (%)	105 (46.9)	101 (46.1)
Prior csDMARDs (any), n (%)	212 (94.6)	208 (95.0)
Baseline csDMARDs (any), n (%)	141 (62.9)	129 (58.9)

