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Spondyloarthritiden (axSpA + PsA)

Adrian Ciurea

LBA 0004

Remote monitoring and patient-initiated care compared to regular face-to-face outpatients visits in axial spondyloarthritis: results from a randomized non-inferiority trial

I. J. Berg, J. Sexton, E. Kristianslund, A. T. Tveter, G. Bakland, L. Gossec, E. A. Haavardsholm, S. Hakim[1], G. J. Macfarlane, E. Moholt, S. Aarrestad Provan, E. E. Kvernberg Thomassen[2], A. De Thurah, S. Lillegraven, N. Osteras

Methods

Objective: To determine whether (a) remote monitoring or (b) patient-initiated care for axSpA were non-inferior to (c) usual care in maintaining low disease activity (ASDAS <2.1) on stable TNFi treatment over 18 months.

Three-armed, single-center, parallel-group, randomized, controlled, open-label non-inferiority trial.

A Usual Care (face-to-face hospital visits every 6 months); N = 82

B Remote Monitoring (monthly digital reporting BASDAI, BASFI; no prescheduled visits); N = 79

If BASDAI<4, patients were contacted and offered consultation.

C Patient-initiated Care (self-monitoring and no prescheduled visits); N = 81

Patients in all groups could contact the study nurse and request a consultation.

Primary endpoint: ASDAS <2.1 at 6, 12, 18 months
Mixed effects logistic regression was used to estimate the group-specific probability of ASDAS <2.1
Non-inferiority margin of 15%.

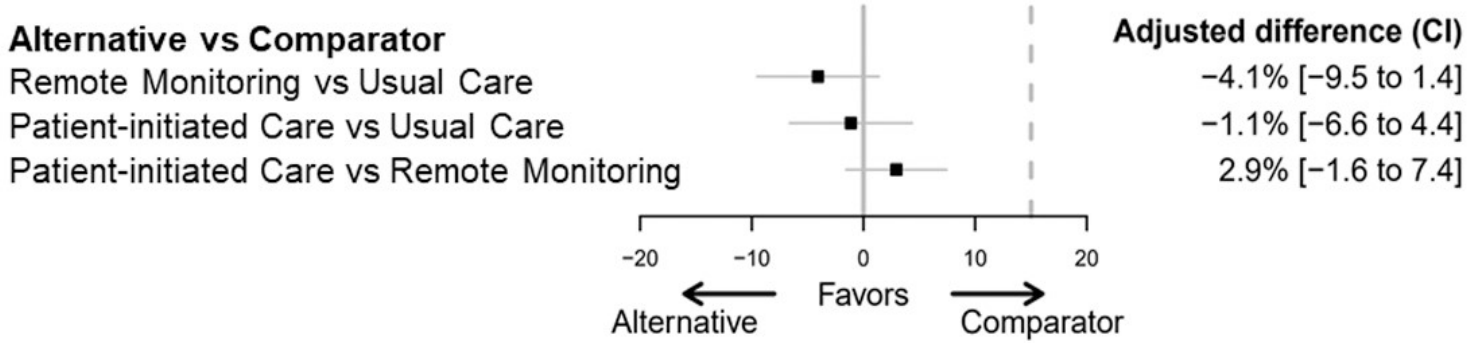
Results

Figure 1 Proportions of patients with ASDAS<2.1 and comparisons of adjusted probability of ASDAS<2.1 between study arms

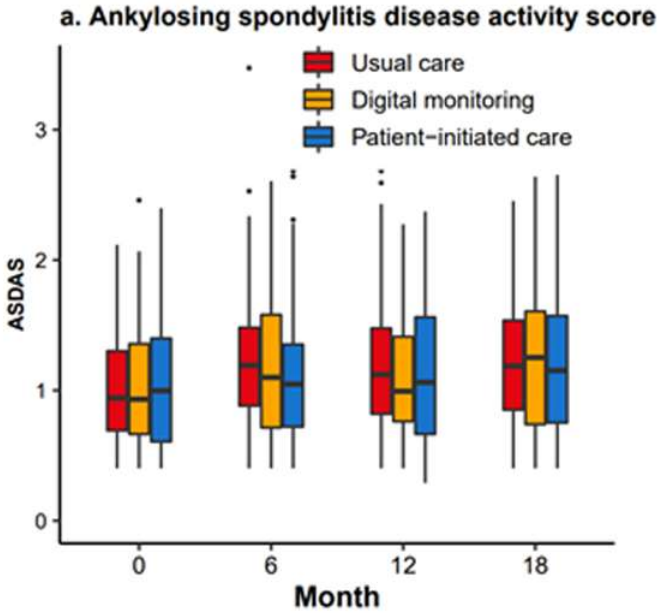
Numbers and proportion of patients with ASDAS<2.1

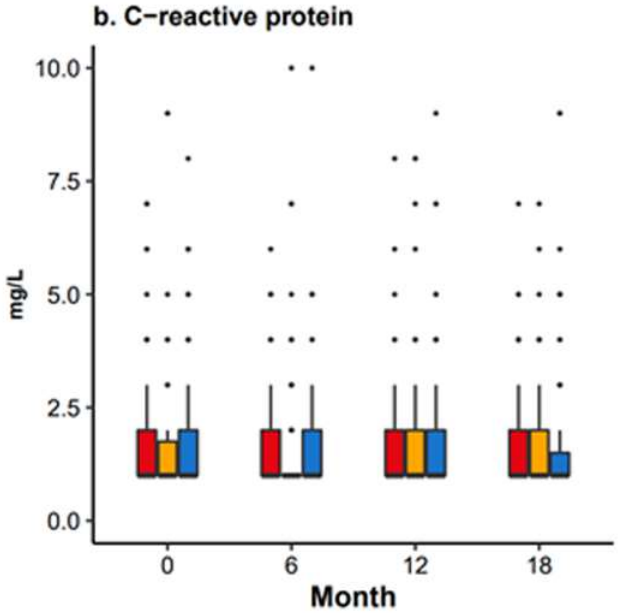
	6 months	12 months	18 months
Usual Care	75 (96%)	70 (93%)	72 (90%)
Remote Monitoring	71 (96%)	70 (96%)	68 (94%)
Patient-initiated Care	68 (92%)	68 (91%)	73 (92%)

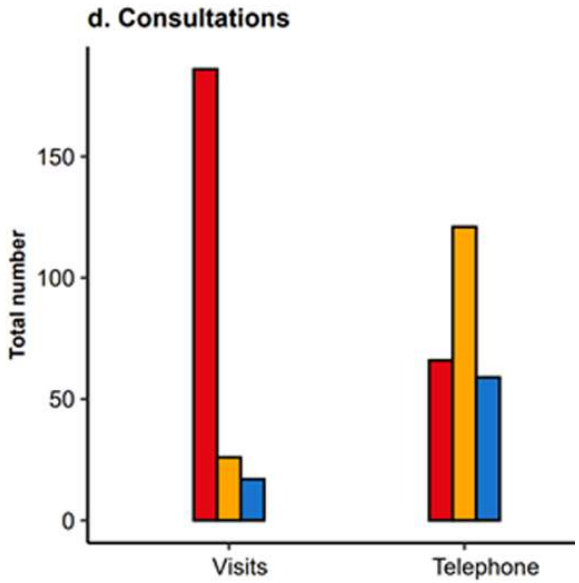
Comparisons of adjusted probability of ASDAS<2.1 between study arms



Results


a. Ankylosing spondylitis disease activity score
Usual care
Digital monitoring
Patient−initiated care
ASDAS
0
1
2
3
0
6
12
18
Month


b. C−reactive protein
mg/L
0.0
2.5
5.0
7.5
10.0
0
6
12
18
Month


d. Consultations
Total number
0
50
100
150
Visits
Telephone

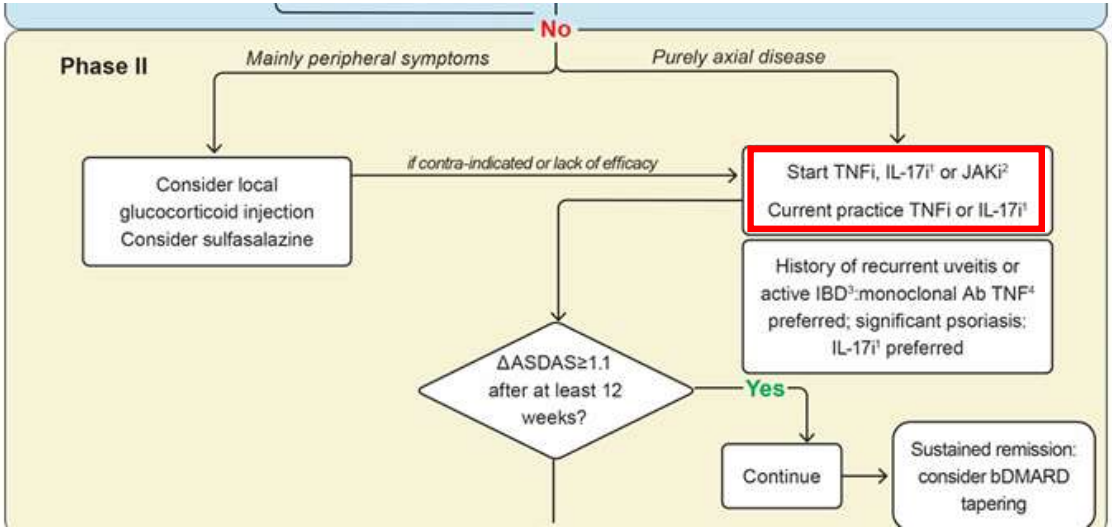
Conclusions

- In this study, Remote Monitoring and Patient-initiated Care were both non-inferior to Usual Care in maintaining low disease activity in axSpA over 18 mo.
- Patient-initiated Care was also non-inferior to Remote Monitoring.
- Such follow-up strategies could be implemented in patients with axSpA and low disease activity, as an alternative to regular outpatient visits to optimize health care resources.

LBA 0002

Secukinumab versus Standard-of-Care in axial spondyloarthritis: A randomized controlled open-label trial for treat-to-target outcomes (ASCALATE)

D. Poddubnyy[1], L. Hammel[2], P. Goupille[3], F. Proft[4], J. Blanchard[5], B. Roesler[6], X. Baraliakos[7]



Ramiro et al. Ann Rheum Dis 2023;82:19-34.

Inclusion criteria: active axSpA and objective signs of inflammation, inadequate response to 2NSAIDs

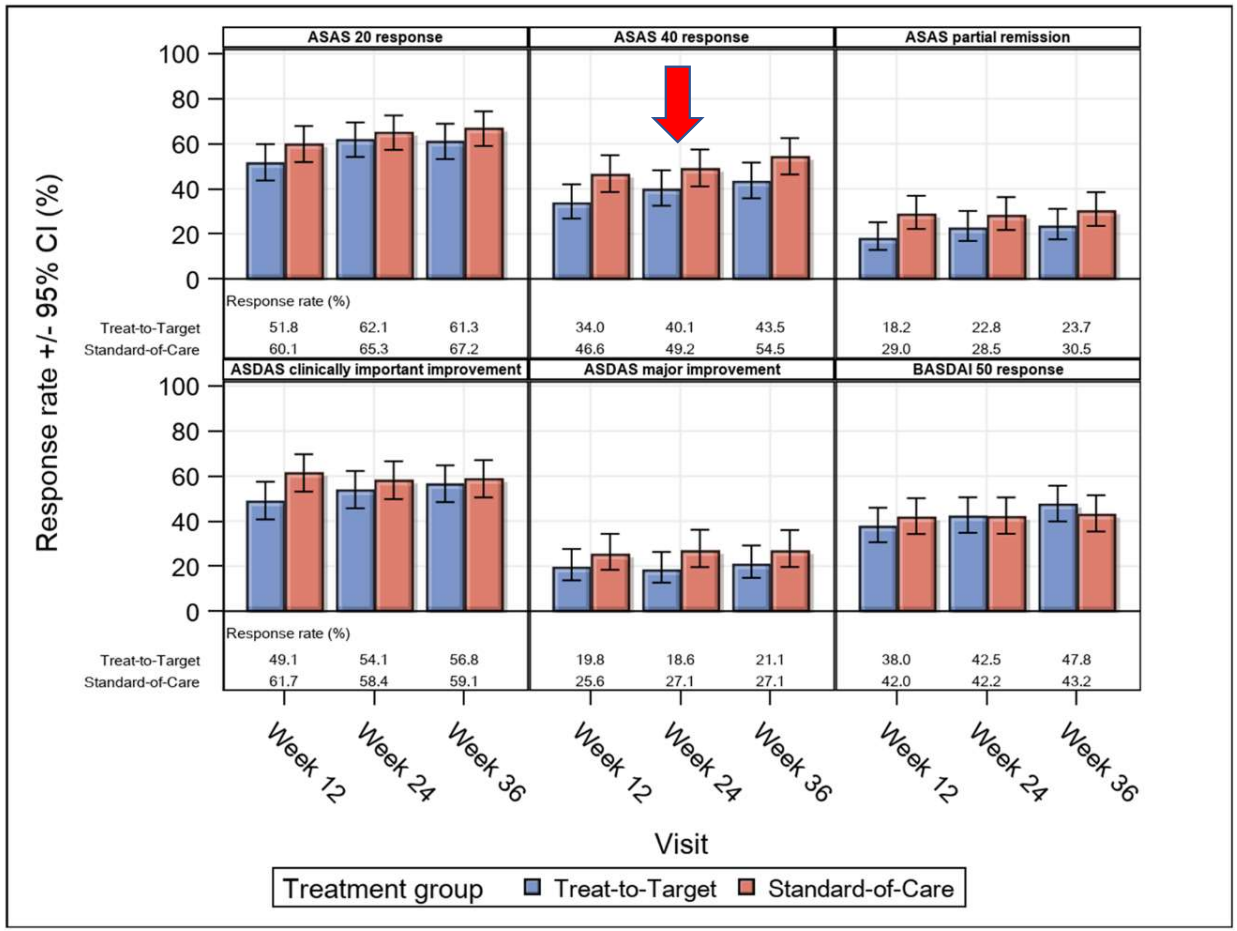
Treat-to-target: SEC 150 mg, week 12: IR (41%) SEC 300 mg; week 24: IR (28%) ADA 40 mg (N = 155)

IR = inadequate responders; patients not achieving clinically important improvement (ΔASDAS ≥1.1) from BL.

Standard of care (N = 149)

78% TNFi, 11% IL17i, 5% csDMARDs, 5% no b/csDMARDs

Figure 1. Response rates for specific binary efficacy endpoints, adjusted for baseline characteristics - bar plots with data from model analysis (Full Analysis Set)



The response rate in treatment groups is adjusted for baseline quick CRP and baseline body weight. Missing values were imputed by non-response (non-responder imputation), i.e., percentages are based on all patients in the analysis set.

Primary endpoint not met
(ASAS40 response week 24):
OR 0.69, 95%CI 0.43-1.10, p=0.12

Conclusions

- With the methodology chosen, the AScalate study did not demonstrate superiority of T2T in axSpA over Standard of Care. Observations are consistent with the TICOSPA trial.

- AxSpA patient care was found to be close to T2T strategy in the participating expert centers.

- SEC dose escalation was beneficial for approximately one third of patients.

POS 0204

Effectiveness of TNF inhibition in Very Early AxSpA (≤1 year of axial symptom duration): Results from a large national observational cohort

A. Ciurea, A. Götschi, B. Möller, M.J. Nissen, Bürki K, R. Bräm, M. Andor, Th. Hügle, A. Rubbert-Roth, D. Kyburz, S. Adler, O. Distler, A. Scherer, R. Micheroli

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

Methods

Objective: To compare the effectiveness of treatment with a first TNF blocker in patients with different axial symptom durations: very early axSpA (≤1y), early axSpA (>1y and ≤2y), and established axSpA (>2y).

Inclusion criteria: SCQM patients with axSpA, start of first TNFi between 2004 and 2023.

Outcomes:

- Drug retention: Cox proportional hazards model
- Treatment response at 12±6 mo: BASDAI-50 and ASAS40 responses
- Analyses adjusted for age, sex, HLA-B27, BMI, education, smoking, elevated CRP, SIJ inflammation on MRI

Results

	Very Early axSpA (≤1 year) N = 131		Early axSpA (>1 & ≤2 years) N = 75		Established axSpA (>2 years) N = 874		p
Parameters	N		N		N		
Male sex, N (%)	131	71 (54.2)	75	33 (44.0)	874	447 (51.1)	0.37
Age, years, mean (SD)	131	37.3 (12.7)	75	40.5 (13.5)	874	43.6 (12.3)	<0.001
Axial symptom duration, years, median (IQR)	131	0.5 (0.3; 0.7)	75	1.4 (1.2; 1.6)	874	10.2 (5.3; 19)	<0.001
HLA-B27 positive, N (%)	117	67 (57.3)	66	32 (48.5)	804	533 (66.3)	0.004
Body mass index, mean (SD)	120	24.7 (4.4)	64	25.7 (4.9)	807	25.8 (4.6)	0.02
Current smoking, N (%)	120	42 (35.0)	70	20 (28.6)	801	266 (33.1)	0.27
Tertiary education, N (%)	108	21 (19.4)	60	16 (26.7)	721	195 (27.0)	0.09
Sacroiliitis on MRI, N (%)	123	72 (58.5)	64	40 (62.5)	766	345 (45.0)	0.001
BASDAI, mean (SD)	97	5.7 (1.9)	47	5.1 (1.8)	612	5.4 (2.0)	0.09
ASDAS, mean (SD)	90	3.5 (0.9)	42	3.1 (0.9)	549	3.3 (0.9)	0.02
Elevated CRP, N (%)	113	57 (50.4)	58	21 (36.2)	703	312 (44.4)	0.2
BASFI, mean (SD)	96	3.9 (2.5)	46	3.1 (2.1)	598	3.7 (2.4)	0.14
BASMI, mean (SD)	106	1.6 (1.4)	50	1.1 (1.0)	657	2.1 (1.9)	<0.001

Results

	Retention Analysis N = 592			BASDAI 50 Response N = 422			ASAS40 Response N = 418		
Parameters	HR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Very early vs. established axspA	1.05	0.67; 1.64	0.84	0.85	0.44; 1.64	0.64	1.55	0.82; 2.92	0.18
Early vs. established axSpA	0.84	0.62; 1.15	0.28	0.79	0.27; 2.25	0.66	0.62	0.18; 1.83	0.4
Age	0.99	0.98; 1.00	0.03	0.98	0.97; 1.00	0.07	0.99	0.97; 1.01	0.4
Female sex	1.53	1.23; 1.90	<0.001	0.49	0.31; 0.78	0.002	0.61	0.39; 0.96	0.04
HLA-B27 negativity	1.27	1.02; 1.58	0.03	0.54	0.33; 0.89	0.02	0.57	0.35; 0.93	0.03
Education secondary	0.89	0.67; 1.17	0.39	2.84	1.45; 5.80	0.003	2.22	1.13; 4.61	0.03
Education tertiary	1.02	0.75; 1.38	0.92	2.54	1.24; 5.44	0.01	2.67	1.29; 5.82	0.01
Body mass index	1.03	1.00; 1.05	0.03	0.95	0.90; 1.00	0.07	0.95	0.90; 1.00	0.05
Current smoking	1.11	0.90; 1.38	0.32	0.84	0.52; 1.34	0.46	0.91	0.57; 1.44	0.69
Elevated CRP	0.57	0.46; 0.71	<0.001	3.03	1.95; 4.74	<0.001	2.12	1.37; 3.31	<0.001
Sacroiliitis on MRI	0.83	0.68; 1.01	0.06	1.42	0.91; 2.22	0.13	1.28	0.82; 1.99	0.28

Conclusions

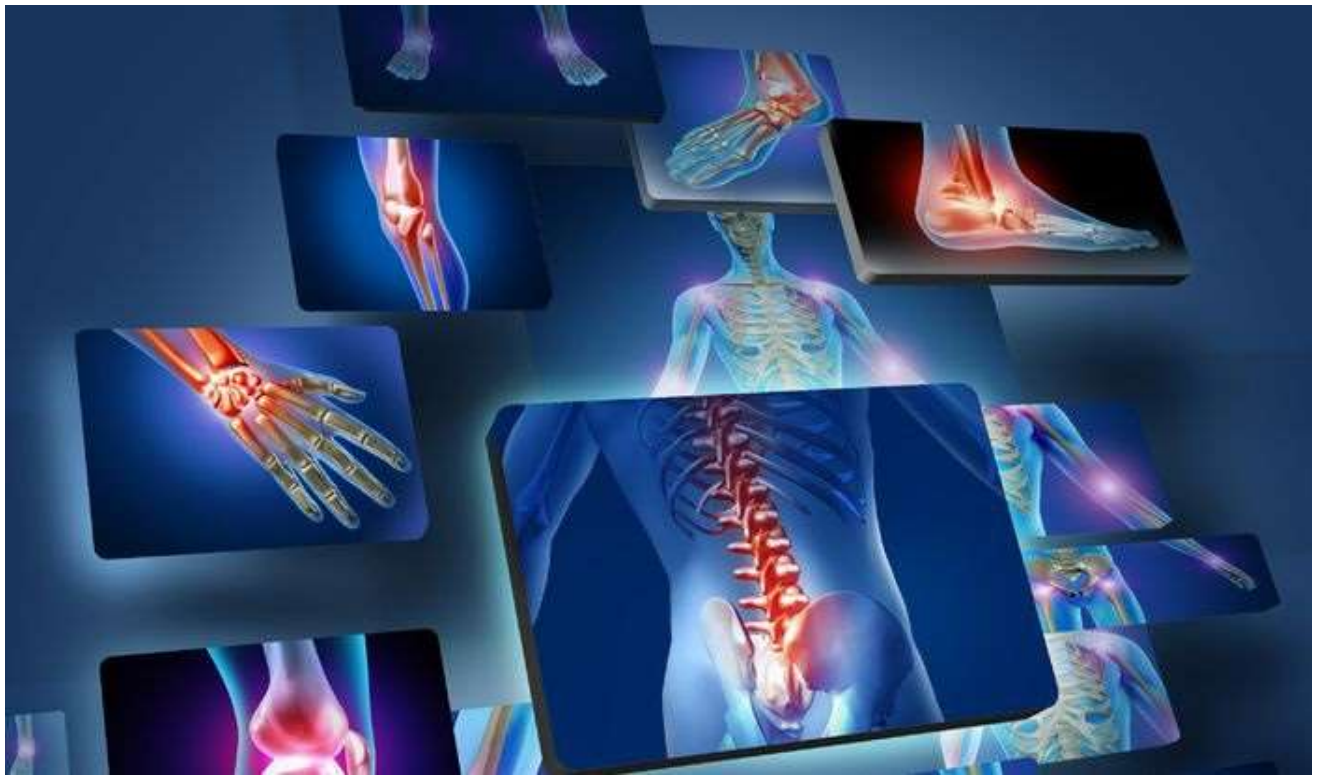
- There is no evidence that Initiating a first TNFi during the very early disease phase leads to better drug retention or better treatment response compared to a later start of treatment.

- Short axial symptom duration as a sole criterion seems not to select those patients responding best to treatment.

- The study highlights the need for additional patient selection criteria to improve treatment response.

- The study also confirms known factors associated with treatment response in axSpA, particularly elevated CRP levels, HLA-B27 positivity and male sex.

Psoriasisarthritis

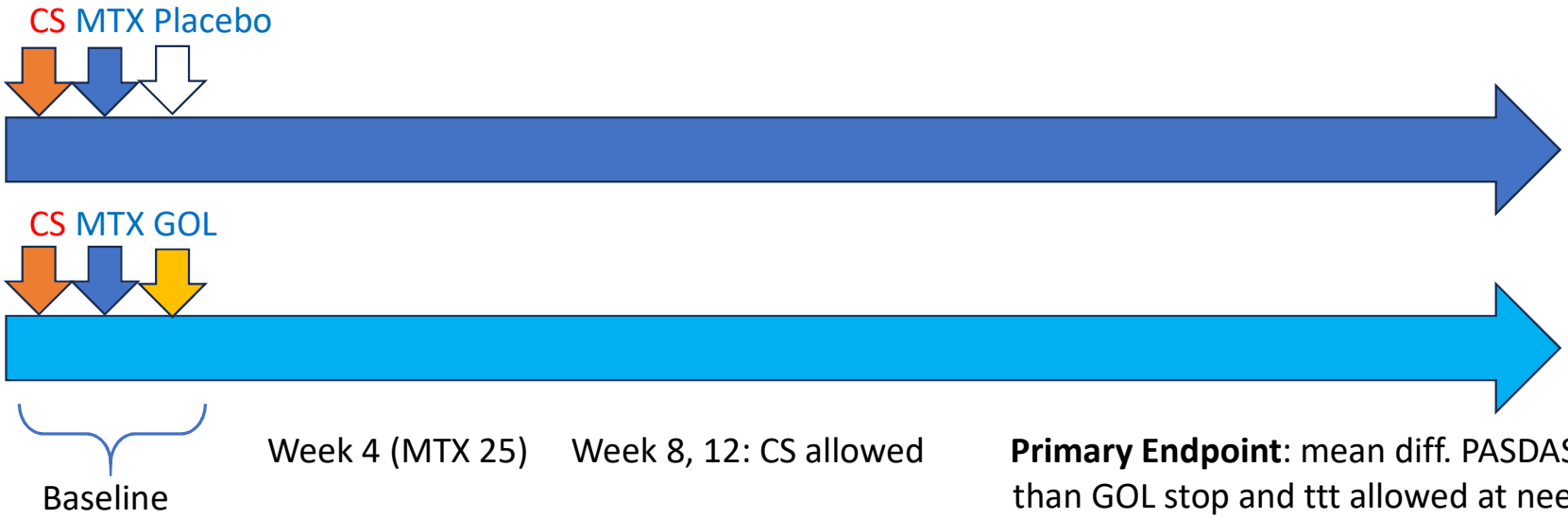


LBA 0002

A treatment strategy combining TNF-inhibitor, methotrexate and steroids versus methotrexate and steroids in early PsA: GOLMEPSA, a randomized, double-blind clinical trial

G. De Marco[1,2], E. Hensor[1,2], P. S. Helliwell[2], S. Sultan[3], S. R. Dubash[1,2,4], X. Michelena[1,2,5], L. C. Coates[6], A. L. Tan[1,2], P. Emery[2], D. Mcgonagle[1,2], H. Marzo-Ortega[1,2]

Methods



Investigator initiated, double-blind, randomized, placebo-controlled, two-armed, parallel-group, single centre, 52-weeks clinical trial.

Inclusion criteria: Adult patients with PsA (CASPAR criteria) of ≤ 24-month duration, ≥ 3 swollen and 3 tender joints or 2 swollen and 2 tender joints plus one tender enthesis (Achilles' tendon or plantar fascia) and naïve to DMARDs (for both PsA and psoriasis)

CS: Methylprednisolone 120 mg i.m. at BL and allowed only at weeks 8, 12 to a maximum of 120 mg (i.m./i.a.)

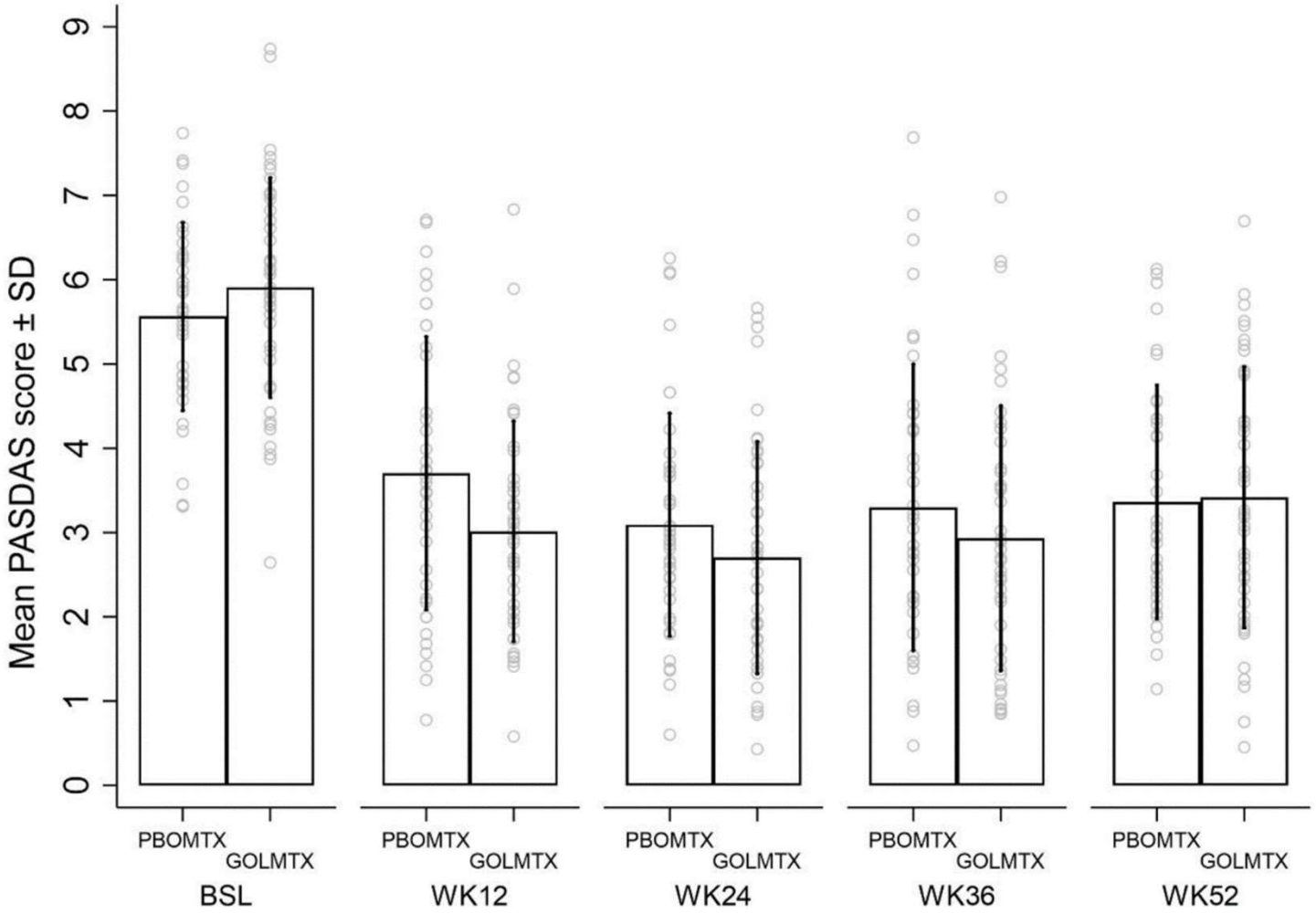
MTX: start with 15 mg and titrated up to 25 mg/week by week 4.

Variable	Allocation		Total N = 84
	Arm 2 (PBO-MTX) N = 41	Arm 1 (GOL-MTX) N = 43	
Age, mean in years (SD; absolute range)	42.9 (12.5; 18-65)	42.1 (12.5; 23-73)	42.5 (12.4; 18-73)
Female gender, n	19 (46.3%)	19 (44.2%)	38 (45.2%)
BMI, mean in kg/m^2 (SD; absolute range)	29.7 (5.8; 19.1-46.7)	29.9 (5.4; 21.3-43)	29.8 (5.6; 19.1-46.7)
Weight ≥ 100 kg	8 (19.5%)	7 (16.3%)	15 (17.9%)
Ethnicity			
White, n	32 (78%)	29 (67.4%)	61 (72.6%)
Other, n	3 (7.3%)	4 (9.3%)	7 (8.4%)
Not stated, n	6 (14.6%)	10 (23.3%)	16 (19%)
Family history of PsA, n	3 (7.3%)	8 (18.6%)	11 (13.1%)
Family history of Psoriasis, n	22 (53.7%)	18 (41.9%)	40 (47.6%)
Never smoker, n	25 (61%)	18 (41.9%)	43 (51.2%)
Joint symptoms duration, median in months (IQR; absolute range)	10.2 (5.2-18.1; 1.7-197.7)	10.1 (5.3-24.1; 1.8-61.5)	10.2 (5.3-21.1; 1.7-197.7)
PsA duration, median in months (IQR; absolute range)	0.5 (0.2-1.3; 0.1-7.3)	0.5 (0.2-2.5; 0.0-7.7)	0.5 (0.2-1.9; 0.0-7.7)
PsA features			
Polyarthritis, n	30 (73.2%)	31 (72.1%)	61 (72.6%)
Axial disease*, n	1 (2.4%)	2 (4.7%)	3 (3.6%)
Dactylitis, n	26 (63.4%)	30 (69.8%)	56 (66.7%)
Entheseal tenderness, n	23 (56.1%)	29 (67.4%)	52 (61.9%)
Skin			
Current Psoriasis, n	25 (61%)	29 (67.4%)	54 (64.3%)
BSA, median percentage (IQR; absolute range)	0.9 (0.3-2.5; 0-20)	1 (0.3-4; 0-48)	1 (0.3-2.9; 0-48)
BSA ≥3%, n	8 (19.5%)	13 (30.2%)	21 (25%)
PASI score, median (IQR; absolute range)	2.6 (0.9-5.1; 0-15.4)	2.5 (0-16; 0-73)	3 (0-12; 0-73)
Psoriatic nail dystrophy, n	25 (61%)	25 (58.1%)	50 (59.9%)
Anti-CCP positive, n	4 (9.8%)	2 (4.7%)	6 (7.1%)
Rheumatoid factor positive, n	4 (9.8%)	2 (4.7%)	6 (7.1%)
Anti-Nuclear autoantibodies positive, n	3 (7.3%)	1 (2.3%)	4 (4.8%)
PASDAS score, mean (SD, range)	5.6 (1.1; 3.3-7.7), n = 40	5.9 (1.3; 2.6-8.7)	5.7 (1.2; 2.6-8.7), n = 83
MDA, n	3 (7.3%)	1 (2.3%)	4 (4.8%)

PBO = Placebo; MTX = Methotrexate; GOL = Golimumab; SD = Standard Deviation; BMI = Body Mass Index; PsA = Psoriatic Arthritis; IQR = Inter-Quartile Range; BSA = Body Surface Area (%); PASI = Psoriasis Area and Severity Index; CCP = Cyclic Citrullinated Peptides; PASDAS = Psoriatic ArthritiS Disease Activity Score; CPDAI = Composite Psoriatic Disease Activity Index; MDA = Minimal Disease Activity; DLQI = Dermatology Life Quality Index

*Determined by clinical judgement

Results


Mean PASDAS score ± SD
0
1
2
3
4
5
6
7
8
9
PBOMTX
GOLMTX
BSL
WK12
WK24
WK36
WK52

Conclusions

- The combination of GOL+MTX was not significantly superior in ameliorating PASDAS-measured disease activity at 24 weeks.
- First line treatment of early, DMARD naïve PsA with MTX 25 mg/week and CS produced effective disease control at week 24 and was well tolerated.
- A low utilisation of bDMARDs was observed at 52 weeks in both groups.

LBA 0002

Early (3-month) and maintained (12-month) comparative effectiveness of 5 different classes of advanced therapies in a large multinational cohort of real-world PsA patients

W. Tillett[1], R. Alten[2], E. Lubrano[3], K. J. Ng[4], M. Ngantcha[4], I. De La Torre[4], D. Kennedy[4], N. Gullick[5,6], D. Mcgonagle[7]

Methods

- The predefined interim analysis presented here aimed to report (1) the baseline characteristics and (2) the comparative effectiveness of PsA treatments at three (M3) and twelve (M12) months.
- 175 sites across six countries
- Propensity score-adjusted comparative analyses weighted by IPTW (Inverse Probability of Treatment Weighting) were powered for evaluating treatment groups above 10% of the total sample.
- Missing data were imputed through simple and multiple imputation.

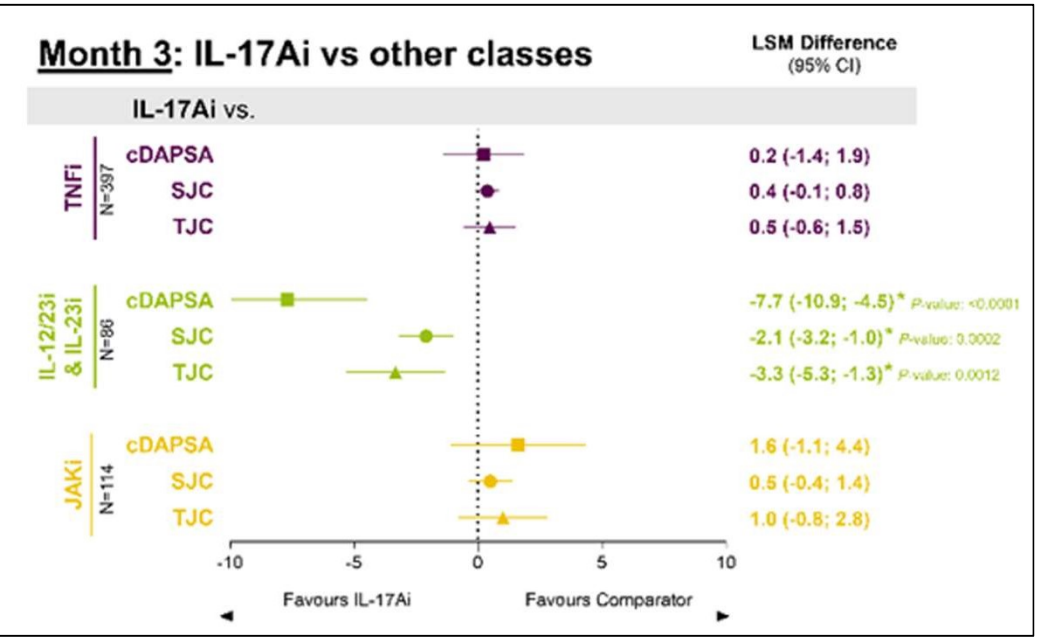
Results

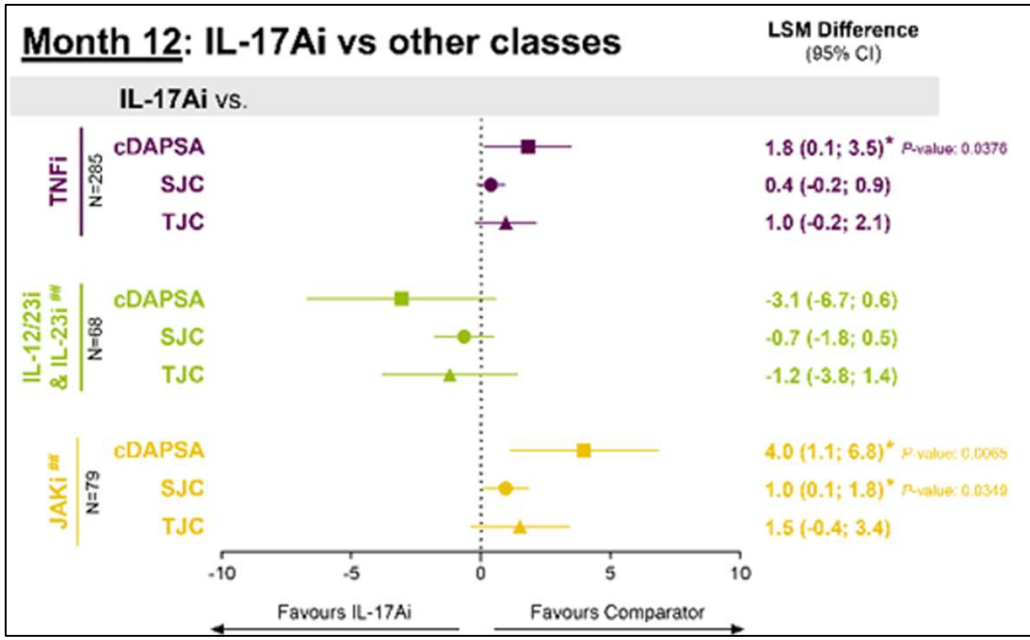
Table 1. Baseline characteristics and descriptive effectiveness at 3 and 12 months of treatment.

		Ixekizumab	Secukinumab 150 mg	Secukinumab 300 mg	TNFi	IL-12/23i	IL-23i	JAKi	PDE4i	Overall
		N=343	*N=86*	*N=78*	*N=437*	*N=34*	*N=56*	*N=124*	*N=32*	*N=1192*
BASELINE DEMOGRAPHICS & CLINICAL CHARACTERISTICS	Age, years, mean (SD)	53.7 (12.2)	53.8 (11.7)	51.0 (12.6)	51.1 (12.3)	50.4 (11.8)	52.7 (11.7)	52.8 (12.3)	54.8 (9.2)	52.4 (12.1)
	Female	221 (64.4%)	57 (66.3%)	46 (59.0%)	263 (60.2%)	19 (55.9%)	33 (58.9%)	81 (65.3%)	20 (62.5%)	740 (62.1%)
	Years since PsA diagnosis, mean (SD)	9.2 (8.5)	8.3 (9.2)	8.5 (7.4)	6.6 (7.3)	8.4 (8.9)	8.9 (8.1)	9.0 (7.6)	8.8 (7.7)	8.1 (8.0)
	b/tsDMARD experienced	241 (70.3%)	46 (53.5%)	63 (80.8%)	137 (31.4%)	25 (73.5%)	43 (76.8%)	90 (72.6%)	6 (18.8%)	652 (54.7%)
	Concomitant csDMARDs	124 (36.2%)	32 (37.2%)	30 (38.5%)	234 (53.5%)	7 (20.6%)	17 (30.4%)	58 (46.8%)	8 (25.0%)	511 (42.9%)
	TJC (0-68), median (range)	8.0 (0 - 60)	7.0 (0 - 65)	9.5 (0 - 52)	7.0 (0 - 65)	7.0 (0 - 32)	8.0 (0 - 52)	8.0 (0 - 66)	4.0 (0 - 47)	8.0 (0 - 66)
	SJC (0-66), median (range)	3.0 (0 - 35)	2.0 (0 - 26)	3.0 (0 - 39)	3.0 (0 - 31)	2.0 (0 - 24)	3.0 (0 - 21)	4.0 (0 - 53)	2.0 (0 - 17)	3.0 (0 - 53)
	cDAPSA, mean (SE)	27.9 (0.9)	25.4 (1.5)	30.7 (2.1)	27.2 (0.8)	24.8 (2.8)	28.0 (2.1)	29.8 (1.6)	20.8 (2.5)	27.6 (0.5)
	BSA ≥3%	134 (39.1%)	30 (34.9%)	28 (35.9%)	132 (30.2%)	15 (44.1%)	29 (51.8%)	32 (25.8%)	13 (40.6%)	413 (34.6%)

Results

Figure 1. Baseline-adjusted and weighted (IPTW) comparative (MMRM) M3 and M12 real-world effectiveness of biologics at improving PsA joint disease activity





cDAPSA: SJC, TJC, Pat-Global, Pat-Pain

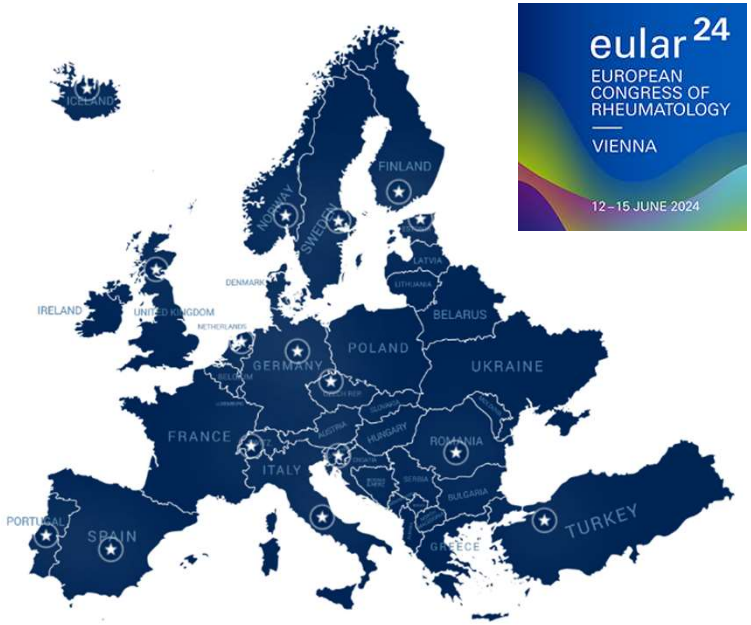
Conclusions

- PRO-SPIRIT captures a heterogeneous sample of patients across six countries and five classes of advanced therapies
- IL17Ai are as effective as TNFi and JAKi at improving joint disease activity in PsA patients.
- IL-17Ai provide faster improvement in cDAPSA scores than either an IL-12/23i or IL-23i, and a clearly greater benefit in BSA than a TNFi.

OP 0034

EUROSPA

Differential joint-level responses to TNF inhibitors in psoriatic arthritis: A collaborative European observational cohort study



Adrian Ciurea[1], Seraphina Kissling[1], Andrea Götschi[1], Lykke Midtbøll Ørnbjerg[2], Simon Horskjær Rasmussen[2], Bálint Tamási[1], Burkhard Möller[1], Michael J. Nissen[1], Bente Glintborg[2], Anne Gitte Loft[2], Joao Madruga Dias[3], Paula Valente[3], Almut Scherer[1], René Bräm[1], Karel Pavelka[4], Jakub Závada[4], Bjorn Gudbjornsson[5], Olafur Palsson[5], Gareth T. Jones[6], Gary J. Macfarlane[6], Catalin Codreanu[7], Corina Mogosan[7], Vappu Rantalaiho[8], Ritva Peltomaa[8], Isabel Castrejon[9], Ziga Rotar[10], Brigitte Michelsen[11], Florenzo Iannone[12], Johan K. Wallman[13], Irene van der Horst-Bruisma[31], Oliver Distler[1], Mikkel Østergaard[2], Merete Lund Hetland[2], Raphael Micheroli[1], Caroline Ospelt[1]

[1]Switzerland, [2]Denmark, [3]Portugal, [4]Czech Republic, [5]Iceland, [6]United Kingdom, [7]Romania, [8]Finland, [9]Spain, [10]Slovenia, [11]Norway, [12]Italy, [13]Sweden, [14]The Netherlands

The EuroSpA Research Collaboration Network

EUROSPA

- **Objective**: To explore potential differences in the rate of resolution of joint swelling upon treatment with a first TNF inhibitor (TNFi) between different joint locations in patients with PsA treated in routine clinical care.
- **9 registries** within the EuroSpA provided data on individual joint counts (28-joint count) in PsA patients: Denmark, Switzerland, Czech Republic, Portugal, Iceland, Finland, Romania, Italy, Turkey.
- **Inclusion criteria**: Diagnosis of PsA, Age ≥18 years; ≥1 swollen joint (out of 28) at start of TNFi in bionaive patients; TNFi either as monotherapy or added to methotrexate.
- **Primary outcome**: time to resolution of joint swelling
- **Method**: Interval-censored mixed-effects Cox proportional hazards models to estimate the hazard (or the rate) of resolution of synovitis between different joint locations; with adjustment for age and sex

EUROSPA

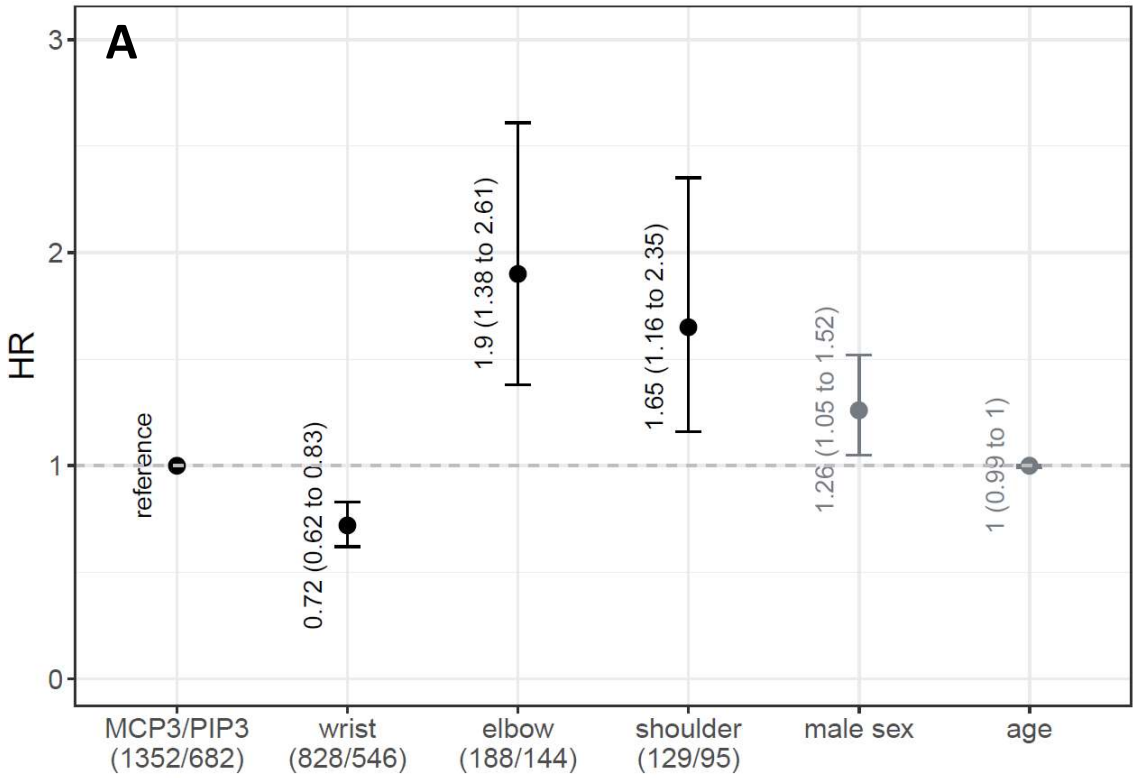
Results (baseline characteristics)

Baseline characteristics	N = 1729
Female sex, N (%)	799 (53.8)
Age, years	49.4 (12.1)
Symptom duration, years	9.0 (8.6)
CRP, mg/l	15.0 (21.5)
DAS28-CRP	4.7 (1.0)
Physician global score	4.9 (2.3)
Patient global score	6.6 (2.3)
Use of methotrexate, N (%)	1323 (76.5)

Details regarding peripheral arthritis	N = 1729
• Tender joints (28 joints count)	7.4 (6.0)
• Swollen joints (28 joints count)	4.9 (4.1)
Number of joints involved (out of 28), N (%)	
• <5	1043 (60.3)
• ≥5	686 (39.7)
Type of joints involved, N (%)	
• Only small joints	1034 (59.8)
• Only large joints	210 (12.1)
• Small and large joints	485 (28.1)

Results (adjusted analyses)

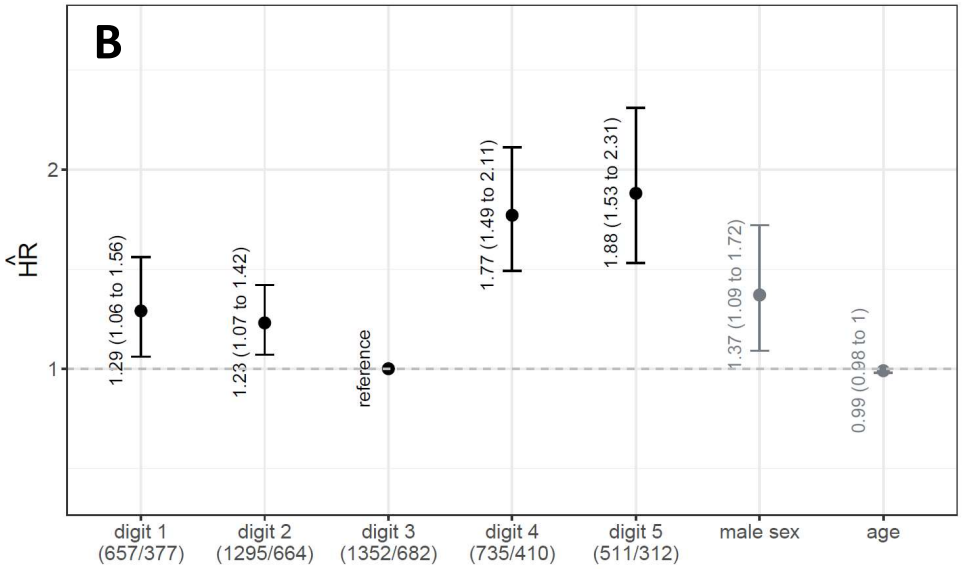
Rate of resolution of swollen joints (HR and 95% CI) after start of TNFi treatment for joints along the proximal-distal axis of the upper limb: shoulder, elbow, wrist, MCP3/PIP3 (ref).



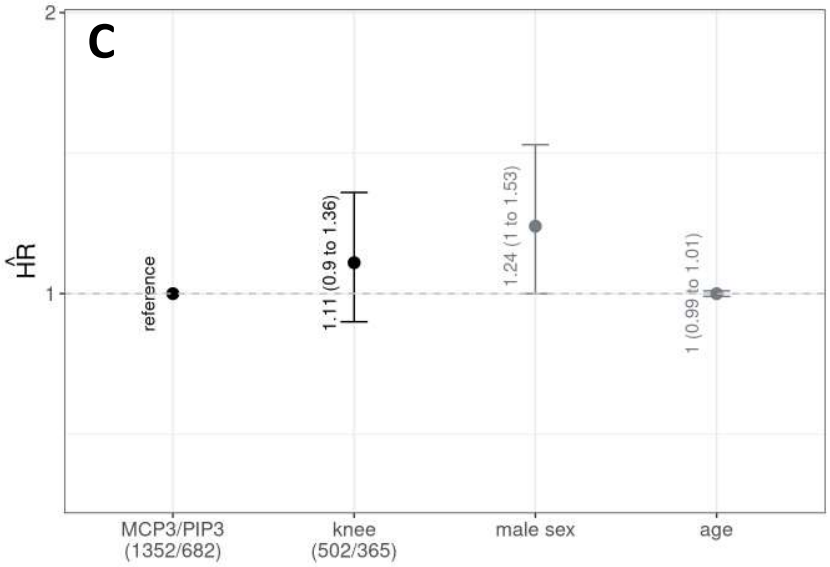
Results (adjusted analyses)

Rate of resolution of swollen joints (HR and 95% CI) after start of TNFi treatment for:

B: finger joints along the anterior-posterior axis of the hand



C: knee compared to joints of digit 3



Conclusions

- The clinical response to TNFi treatment in PsA seems to be dependent on the specific joint location.
- The most favourable responses were observed in the proximal joints of the upper limb and the MCP and PIP joints of digits 4 and 5, when compared to digit 3.
- The differences seem not to be due to the size of the joint (volume of synovitis) or to mechanical stress.
- Whether this differential response is related to the recently described transcriptomic, epigenomic, and phenotypical differences between synovial fibroblasts at different joint locations remains unclear.[1-3]

[1]Nat Commun 2016;7:11849.
[2]Nat Commun 2017;8:14852.
[3]Nat Commun 2023;14:8172.