Abstract SAT0320 – Table 2. Inter-reader reliability and agreement analysis of MASEI components. All items were categorised as yes/no. N/A not applicable since one of the lectors offers the same result for all cases, so kappa can't be calculated in this item due to sparse differences between lectors. N/B enthesitis without bursa.

		Abnormal tendon structure	Thickened tendon	Erosion	Enthesitis calcification	Enthesitis PD	Bursitis
Triceps tendon enthesitis	Mean kappa	0.648 ± 0.104	0.606 ± 0.103	0.808 ± 0.160	0.579 ± 0.119	0.628 ± 0.193	N/B
	Mean agreement	83.95%	86.42%	95.53%	80.25%	95.06%	
Quadriceps tendon enthesitis	Mean kappa	0.529 ± 0.103	0.580 ± 0.100	1.000 ± 0.000	0.487 ± 0.115	0.610 ± 0.110	N/B
	Mean agreement	76.55%	79.01%	100%	78.88%	82.71%	
Proximal patellar ligament enthesitis	Mean kappa	0.507 ± 0.116	0.671 ± 0.100	0.475 ± 0.181	0.230 ± 0.094	0.732 ± 0.137	N/B
	Mean agreement	77.77%	83.95%	88.89%	58.03%	93.83%	
Distal patellar ligament enthesitis	Mean kappa	0.258 ± 0.153	0.493 ± 0.125	1.000 ± 0.000	0.438 ± 0.122	0.885 ± 0.069	N/A
	Mean agreement	80.25%	81.48%	100%	77.77%	95.06%	95.03%
Achilles tendon enthesitis	Mean kappa	0.474 ± 0.106	0.784 ± 0.094	0.953 ± 0.046	0.407 ± 0.146	0.812 ± 0.088	0.782 ± 0.113
	Mean agreement	72.84%	91.36%	98.77%	81.48%	92.59%	93.83%
Plantar aponeurosis enthesitis	Mean kappa	0.437 ± 0.119	0.752 ± 0.088	1.000 ± 0.000	0.171 ± 0.058	N/A	N/B
	Mean agreement	72.84%	87.04%	100%	45.68%	98.77%	

Conclusions: MASEI has demonstrated to be a reliable tool in PsA. Erosions and PD showed the best reliability values. Evaluating different definitions of enthesitis PD, signal in the tendon was the most reliable one, followed with minimal differences by PD MASEI and PD OMERACT, and in last place PD bursa.

Disclosure of Interest: None declared

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SAT0321 IXEKIZUMAB TREATMENT SIGNIFICANTLY IMPROVES ENTHESITIS AND DACTYLITIS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS FROM THE SPIRIT TRIALS

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease with heterogeneous musculoskeletal manifestations including enthesitis and dactylitis. Ixekizumab (IXE), an interleukin-17A antagonist, is approved in the USA for the treatment of PsA including patients with pre-existing enthesitis or dactylitis.

Objectives: To investigate the impact of IXE treatment on the resolution of enthesitis or dactylitis and whether such improvements were associated with improved function and health-related quality of life (HRQoL).

Methods: Patients with active PsA who were biologic-naïve (SPIRIT-P1; NCT01695239) or with prior inadequate response to tumour necrosis factor inhibitor(s) (SPIRIT-P2; NCT02349295) were randomised to placebo (PBO) or 80 mg IXE every 4 weeks (IXEQ4W) or 2 weeks (IXEQ2W), after a 160 mg starting dose. All patients who were inadequate responders at Week 16 received rescue therapy (changes in background therapy). Leeds Enthesitis Index (LEI), Leeds Dactylitis Index-Basic (LDI-B), Health Assessment Questionnaire Disability Index (HAQ-DI), and EuroQoL-5D Visual Analogue Scale (EQ-5D VAS) were measured at Week 24. Missing data or data from inadequate responders were considered non-response or imputed with last observation carried forward for categorical and continuous measures, respectively. Statistical comparisons between PBO and IXE treatment groups were performed with a logistic regression model using Wald's test with treatment and study as factors. In post hoc-analyses, associations between enthesitis and dactylitis with HAQ-DI and EQ-5D VAS are based on an ANCOVA model adjusting for study and Disease Activity of Psoriatic Arthritis (DAPSA).

Results: In the integrated SPIRIT-P1 and -P2 dataset (n=679), 403 patients (59% of total) had baseline enthesitis (LEI >0) with a mean 2.9 LEI score, and 155 patients (23% of total) had baseline dactylitis (LDI-B >0) with a mean 56.4 LDI-B score. Relative to PBO, IXE treatment resulted in significantly higher resolution of enthesitis (SPIRIT-P1) and dactylitis (SPIRIT-P1 and -P2) after 24 weeks.^{1,2} In the integrated SPIRIT-P1 and -P2 dataset, both IXEQ4W and IXEQ2W had significantly higher enthesitis and dactylitis resolution than PBO treatment at Week 24 (Table). In ad-hoc analysis, IXE treatment had significantly higher resolution of enthesitis compared to PBO at the enthesal points comprising the LEI score (Table). For all PBO- and IXE-treated patients at Week 24, least squares mean (SE) HAQ-DI changes from baseline were -0.44 (0.05) and -0.25 (0.03; p<0.01) for patients who did and did not resolve enthesitis, and -0.41 (0.06) and -0.31 (0.07; p=0.34) for patients who did and did not resolve dactylitis. Corresponding EQ-5D VAS improvements were 12.3 (2.2) and 5.8 (1.5; p=0.02) for patients who did and did not resolve enthesitis, and 10.8 (2.8) and 9.8 (3.5; p=0.83) for patients who did and did not resolve dactylitis.

Abstract SAT0321 – Table 1. Enthesitis and Dactylitis Resolution from the Integrated SPIRIT-P1 and SPIRIT-P2 Dataset (Week 24)

	PBO	IXEQ4W	IXEQ2W
LEI=0	26/126 (21%)	53/136 (39%)*	49/141 (35%)*
Lateral epicondyle=0	24/79 (30%)	39/85 (46%)*	39/86 (45%)*
Medial femoral condyle=0	23/79 (29%)	41/92 (45%)*	45/100 (45%)*
Achilles tendon insertion=0	19/64 (30%)	37/75 (49%)*	38/74 (51%)*
LDI-B=0	10/42 (24%)	52/67 (78%)*	30/46 (65%)*

Data presented as n/N (%). N=patients with baseline enthesitis (LEI>0), depicted enthesal points, or dactylitis (LDI-B>0); n=responding patients. *p<0.05; **p<0.01

Conclusions: Treatment with IXE resulted in significant improvement in enthesitis and dactylitis in patients with pre-existing enthesitis or dactylitis. Resolution of enthesitis symptoms was associated with improvements in patients' function and HRQoL.

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SAT0322 THE EFFECT OF GUSELKUMAB ON DACTYLITIS: RESULTS FROM A PHASE 2 STUDY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: In a Phase 2 study, Guselkumab (GUS) was shown to be safe and effective in patients (pts) w/active psoriatic arthritis (PsA).

Objectives: To evaluate the effect of GUS on dactylitis in a subset of pts w/dactylitis at baseline (BL) in the phase 2 PsA study of GUS.

Methods: Pts w/active PsA and ≥3% body surface area of plaque psoriasis, despite current or previous treatment, were randomised 2:1 to receive 100 mg subcutaneous GUS at wks 0, 4 then every 8 weeks (wks, q8w) or placebo (PBO) during a 24wk double-blind treatment period. At wk16, pts w/<5% improvement in swollen and tender joint counts early escaped (EE). At wk24, the PBO group crossed over to receive GUS (wks 24, 28 then q8w) (PBO→GUS) and the GUS group continued receiving GUS (GUS→GUS) through wk44. Dactylitis was assessed by scoring each digit from 0–3 (0=absent, 1=mild, 2=moderate, 3=severe), for a combined score of 0–60. Sensitivity analysis of change from BL through wk24 in dactylitic digits was performed (combined score 20). Dactylitis scores during the 24-wk double-blind treatment was analysed using LOCF imputation for missing data and EE. Dactylitis after wk24 was evaluated using observed data.

Results: Of 149 pts, 81 presented w/dactylitis at BL (PBO n=23, mean[SD]=3.9 [3.01]; GUS n=58, mean[SD]=6.5 [6.15]) and 66 continued to the active treatment period (PBO→GUS n=16; GUS→GUS n=50). The dactylitis subset was similar to the overall population in BL characteristics except for higher median values for # of swollen joints, # of tender joints, and CRP. At wks 16 and 24, the GUS group had a significantly greater reduction in the dactylitis score (wk24 mean [SD] change from BL, PBO: -0.4 [6.06]; GUS: -3.8 [4.93]; p=0.006) and a greater % of pts w/dactylitis resolution, compared to the PBO group (figure 1). Consistent results were obtained w/the # digits w/dactylitis (wk24 mean [SD] change from BL, PBO: -0.2 [3.04]; GUS: -2.1 [2.21]; p=0.003). Improvement in dactylitis seen at wk24 was maintained in the GUS→GUS group (wk56: mean[SD] change from BL = -5.5 [4.84], 75% of pts w/resolution) and the values for the PBO→GUS group (wk56: mean[SD] change from BL = -4.4 [3.50], 93.7% of pts w/resolution) approached those of the GUS→GUS group. Improvement in dactylitis was greater in ACR20/ACR50 responders vs non-responders in GUS-treated patients (Table

1) and was significantly correlated with improvement in TJC ($R=0.38$, $p=0.004$), SJC ($R=0.50$, $p<0.0001$), and HAQ-DI score ($R=0.33$, $p=0.013$).

Abstract SAT0322 – Table 1. Change in Dactylitis Score in ACR20/50 and PASI75 Responders and Non-responders

	Mean (SD) change from BL in Dactylitis Score at Wk24		
	Non-responders	Responders	p-value
ACR 20	-1.76 (7.595), n=21	-4.94 (4.666), n=36	0.044
ACR 50	-2.44 (6.213), n=36	-6.05 (5.133), n=21	0.027
PASI 75	-4.00 (2.858), n=13	-3.70 (6.736), n=44	0.924

Figure 1. Proportion of Patients with Dactylitis Resolution over Time

Conclusions: GUS is efficacious in resolving symptoms of dactylitis in pts w/ active PsA. This effect on dactylitis is correlated with improvement in joint symptoms and physical function.

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SAT0323 ADVERSE DRUG REACTIONS RELATED TO DISEASE-MODIFYING DRUGS (DMARD) IN PSORIATIC ARTHRITIS PATIENTS IN DAILY CLINICAL PRACTICE

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Background: Psoriatic arthritis (PsA) benefits from DMARDs and to know more about the adverse drug reactions (ADRs) represent an advance for the management and safety of these patients in clinical practice.

Objectives: To evaluate the discontinuation due to ADRs of DMARDs used in PsA patients and to analyse the possible associated factors.

Methods: Retrospective longitudinal observational study. **Subjects:** inception cohort of patients from January 2010 to December 2014 and followed up to December 2016, diagnosed with PsA according to ICD-10 code. **Main outcome:** discontinuation of conventional synthetic DMARDs (csDMARDs) and biological originator DMARDs (boDMARDs) due to ADR (moderate: drug suspension regardless of the repercussions, severe: hospital admission required or death). **Covariables:** sociodemographic and clinical. **Statistical analysis:** To estimate DMARDs discontinuation rates, survival techniques were used, expressing the incidence rate (IR) per 100patients*year with their respective CI at 95%. Multivariate Cox regression models were performed to analyse the factors associated with DMARDs discontinuation due to ADRs and results were expressed in Hazard ratio(HR) and 95% CI.

Results: 191 patients were included, with a follow-up of 379.70 Patients*year. 50.3% were male, mean age at diagnosis was 50±14.6 years old. 46.6% of the patients had a history of cutaneous psoriasis. HLA-B27 was positive in 20% of patients. Throughout the follow-up, all patients received csDMARDs and 23 used boDMARDs. Methotrexate(MTX) was the most used drug 69.7%. 30% were on combination therapy, the most frequent was antiTNF +MTX. There were 44 discontinuations due to ADRs, IR 11.59 [8.62–15.57] and 3 were severe, requiring hospital admission (two infections and one cancer), no deaths were recorded. Among the most frequent causes of discontinuation related to ADRs were digestive intolerance 32%, nonspecific manifestations 11%, infections 9% and abnormal transaminase levels 9%. Table1 shows the DMARDs discontinuation rates due to ADRs. In the final discontinuation model related with ADRs (Table2), we observed that distress, high disease activity, corticosteroids at diagnosis and combination therapy were associated with a higher rate of discontinuation.

Table1	Patients*years	Events (n)	IR	95% CI
MTX	243.46	23	9.45	
Salazopyrine	84.80	14	16.51	
Leflunomide	21.83	10	27.48	
Antimalarials	25.34	8	15.78	
boDMARDs	57.56	5	8.69	
Combination therapy	101.76	16	15.72	

Table2	HR	95% CI	P
Women	1.38	0.61–3.09	0.436
Age at diagnosis	0.97	0.94–1.00	0.103
Distress level	3.78	1.85–7.71	0.000
C Reactive protein≥1.05 gr/dL	2.31	1.02–5.20	0.043
corticosteroids at diagnosis	2.66	1.10–6.40	0.029
Combination therapy	2.23	1.14–4.38	0.020
boDMARD	0.32	0.08–1.27	0.105
MTX vs rest of DMARD	0.42	0.19–0.92	0.032

Conclusions: The discontinuation rate due to ADRs was 11.59, although most of them did not have an important clinical impact. We have found some psychological, clinical and treatment factors that can modify the DMARDs survival on PsA patients. We also observed that MTX, seems to be safe in the treatment of PsA, presenting the lowest probability of suspension related to ADRs compared with the rest of treatments.

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