Table 1. PICOS criteria according to PRISMA methodology.

Participants	Adults > 18 years old, Psoriatic Arthritis defined to CASPAR classification criteria (2006) or Moll Wright criteria (1973)
Intervention	Any type of physical activity regardless of intensity and duration
Comparison	Control group (not mandatory)
Outcomes	Level of physical activity Disease activity score Comorbidities
Study design	No restriction

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IMPLEMENTATION OF THE OMERACT PSAMRIS IN A PHASE IIB, RANDOMISED PLACEBO-CONTROLLED STUDY OF ABATACEPT IN PSORIATIC ARTHRITIS

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Background: The semi-quantitative Outcome Measures in Rheumatology (OMERACT) Psoriatic Arthritis Magnetic Resonance Imaging Score (PsAMRIS) was developed for the evaluation of inflammatory and destructive changes in PsA,¹ but has limited trial usage.

Objectives: To retrospectively utilise the PsAMRIS in a multi-dose, randomised Phase IIB study of abatacept in patients with PsA who have inadequate response to DMARDs (NCT00534313).²

Methods: Patients were randomised to abatacept (3, 10 or 30/10mg/kg [the 30-mg/kg group switched to 10mg/kg after the first two doses]) or placebo and treated for 169 days, after which all patients received abatacept 10mg/kg through to Day 365. MRI scans of one hand or foot from 123 patients with PsA collected at baseline and on Days 85, 169 and 365 were centrally evaluated by two readers blinded to chronological order and treatment arm. Synovitis, bone oedema, tenosynovitis, periarticular inflammation, bone erosion, bone proliferation and joint space narrowing were assessed as per OMERACT PsAMRIS; a novel total inflammation score was calculated from the sum of synovitis, bone oedema, tenosynovitis and periarticular inflammation. Variables were analysed using all cases (hand or foot) and by hand and foot cases separately.

Results: At Day 169, the abatacept 30/10mg/kg or 10mg/kg group showed the most decrease (improvement) in each inflammatory assessment (Figure 1). The Day 169 change from baseline severity in synovitis and tenosynovitis in the abatacept 30/10mg/kg and 10mg/kg groups, respectively, were significantly reduced (improved) compared with placebo (estimated differences of -0.966 [p=0.039] and -1.652 [p=0.014], respectively) (Table 1). Patients originally randomised to placebo and then switched to abatacept 10mg/kg at Day 169 showed significant improvements in synovitis, tenosynovitis and total inflammation from Day 169 to Day 365 (Table 1, Figure 1). The structural outcomes joint space narrowing and bone erosion remained stable within each treatment group, showing little change from baseline to Days 85, 169 and 365. After separating hand and foot analyses (72 hand and 51 foot cases), only hand tenosynovitis in the 10-mg/kg group and foot synovitis in the 3-mg/kg group were significantly reduced (improved) at Day 169 compared with placebo (differences of -2.331 [p=0.017] and -1.689 [p=0.010], respectively). In general, more comparisons in the hand analysis were statistically significant versus in the foot analysis.

Conclusion: This analysis confirmed the efficacy of abatacept 10 and 30/10mg/kg when assessed with the OMERACT PsAMRIS. The inflammatory pathologies, synovitis and tenosynovitis, appeared to be the most responsive MRI outcomes.

Analysing hand and foot cases together yielded results consistent with the primary clinical efficacy endpoint (ACR20 response rate), as the abatacept 10- and 30/10-mg/kg groups showed significant differences versus placebo at Day 169;² reduced sample size in separate hand and foot assessments may have prevented finding significant results corresponding to the combined analysis. These results also demonstrate the responsiveness of the PsAMRIS in PsA randomised clinical trials.

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Table 1. MRI variables showing significant treatment effects^a

Between groups at Day 169					
MRI score	Comparator	Comparator	Difference	SE	p value
Synovitis	Placebo	Abatacept 30/10 mg/kg	-0.966	0.461	0.039
Tenosynovitis	Placebo	Abatacept 10 mg/kg	-1.652	0.662	0.014
Placebo group before/after switch ^b					
MRI score	Treatment, Day 169	Treatment, Day 365	Difference	SE	p value
Synovitis	Placebo	Abatacept 10 mg/kg	-1.018	0.458	0.029
Tenosynovitis	Placebo	Abatacept 10 mg/kg	-0.940	0.390	0.018
Total inflammation	Placebo	Abatacept 10 mg/kg	-2.275	1.067	0.036

^aBased on change from baseline at the stated time points (unadjusted p values).

^bPatients were switched to abatacept 10 mg/kg after Day 169.

Figure 1. Change in PsAMRIS assessments of inflammation

^aAll patients switched to abatacept 10 mg/kg after Day 169.

^bSignificant change from baseline based on least squares mean and 95% CI.

^cSignificant difference in change from baseline from Day 169 to Day 365, based on unadjusted p value <0.05.

PsAMRIS=Psoriatic Arthritis Magnetic Resonance Imaging Score.

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