dropped out for various reasons, including adverse events (33%). Thirty-one persons are still being followed, but of these 10 stopped study medication after a median of 3 months. The main reason to discontinue therapy was side effects (80%), notwithstanding a standardized approach for dose reduction and temporary discontinuation as needed.

Conclusion: In this RCT in persons at risk for RA we identified a major obstacle to the successful conduction of such trials, namely the difficulty to enter and retain participants. The primary reported reason was unwillingness to use study medication. This is different from many successfully completed trials on optimal medical treatment in early RA patients, where large inclusion goals have been met within a relatively short timeframe and adherence overall was good. This issue is highly relevant to the current inclination to move the start of drug intervention in RA to ever earlier phases. Further research into patients' motivation and barriers for participation in intervention trials in the at risk phase of RA is necessary to enable intervention research in this phase of the disease.

Figure 1

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AB0287

BENEFITS OF PAIN RELIEF ON FATIGUE, FUNCTION, AND QUALITY OF LIFE WHEN JOINT INFLAMMATION IS CONTROLLED IN PATIENTS WITH RA

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Background: The ultimate goals for rheumatoid arthritis (RA) treatment are to achieve disease activity control and the best potential health state throughout the course of disease.¹ In prior analyses of the Phase 3 trial, RA-BEAM (NCT01710358), baricitinib was associated with significant clinical improvements and patient-reported pain relief in RA patients (pts) who had had an inadequate response to methotrexate.^{2,3} The additional benefits of pain relief when inflammation is controlled are not well characterized.

Objectives: To quantify the contribution of pain relief to other PROs, fatigue, physical function, and quality of life, in pts who achieved control of inflammation, defined as swollen joint count (SJC) ≤ 1 and C-reactive protein (CRP) ≤ 1 mg/dL, at Week (Wk) 24 in a post hoc, pooled analysis of RA-BEAM.

Methods: Among pts with inflammation control, PROs were compared between pts who also achieved thresholds of pain relief at Wk 24 vs those who did not. Pain was measured with a visual analogue scale (VAS, range: 0-100 mm) and divided into ≤ 20 , >20 , ≤ 40 , >40 mm.^{4,5} PROs included: the Health Assessment Questionnaire-Disability Index (HAQ-DI) normative value (<0.5), to compare with a general population, and minimum clinically important differences (MCID, ≥ 0.22), SF-36 physical and mental component scores (PCS and MCS) MCID (≥ 5), and Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F, range of 0-52, higher scores represent less fatigue) normative value (≥ 40.1) and MCID (≥ 3.56). Logistic regression models were adjusted for age, gender, BMI, geographic region, duration of disease, baseline SJC, baseline pain, and baseline value of PRO under evaluation. Missing data were imputed using modified last observation carried forward.

Table 1.

Percentage of patients achieving improvement in PROs by pain relief thresholds in patients who achieved control of inflammation at Week 24

	20 mm threshold		p-values	40 mm threshold		p-values
	≤ 20 mm (N=212)	>20 mm (N=159)		≤ 40 mm (N=297)	>40 mm (N=74)	
HAQ-DI <0.5	67	19	<0.0001	56	7	<0.0001
HAQ-DI MCID, 0.22	89	72	<0.0001	84	73	<0.0001
SF-36 PCS MCID, ≥ 5	81	57	<0.0001	74	58	<0.0001
SF-36 MCS MCID, ≥ 5	48	44	<0.05	47	44	<0.05
FACIT-F ≥ 40.1	80	41	<0.0001	71	32	<0.0001
FACIT-F MCID, ≥ 3.56	77	64	<0.0001	71	70	<0.01

FACIT-F: the Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI: Health Assessment Questionnaire-Disability Index; MCID: minimum clinically important difference; MCS: mental component score; SF-36: 36-Item Short Form Health Survey; PCS: physical component score

Results: Of the total 1305 patients in RA-BEAM, 371 pts treated with adalimumab (121/330), baricitinib (187/487), or placebo (63/488) and background methotrexate achieved inflammation control at Wk 24. Among patients who achieved inflammation control, those who also achieved each pain relief threshold were statistically significantly more likely ($p < 0.05$) to report benefit in physical function, general quality of life, and fatigue than patients who did not reach the pain relief thresholds. (Table)

Conclusion: When inflammation is controlled (SJC ≤ 1 and CRP ≤ 1 mg/dL), more pain relief is associated with better physical function, quality of life, and reduced fatigue. This may support consideration of pain relief as an additional goal of therapy, even when inflammation is controlled. Further investigation should evaluate this benefit with other patient populations and outcomes.

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