started in 2016 to clarify the correlation between RA disease activity and sarcopenia.
Objectives: We investigated risk factors for developing sarcopenia in patients with RA.
Methods: We analysed baseline and 1 year data from the CHIKARA study. The body composition (body weight, muscle mass, fat mass, predicted bone mass, etc.) of 100 patients (78% women; mean age, 68 years) enrolled in this study was examined using a body composition analyzer (MC-780A; TANITA, Tokyo, Japan). Grip strength and walking speed were also measured. Laboratory data, disease activity, Health Assessment Questionnaire (HAQ) and treatment were investigated. Sarcopenia was diagnosed using the criteria of the Asia Working Group on Sarcopenia. Patients with sarcopenia onset at 1 year were detected and their characteristics were analysed. Predictors for development of sarcopenia were also investigated by uni- and multivariate analyses.
Results: Nine patients developed sarcopenia during 1 year. Glucocorticoid (GC) use was significantly more frequent among patients with sarcopenia onset (55.6%) than among those without sarcopenia onset (22.1%, p=0.029). Univariate analysis revealed that GC dosage (r=0.217, p=0.035), body fat mass at baseline (r=−0.211, p=0.040) and change in CRP at 1 year (r=−0.205, p=0.046) were significantly associated with sarcopenia onset. GC use >2 mg/day (Odds ratio (OR) 8.0, 95% confidence interval (CI) 1.2–54.8, p=0.034) and body fat mass (OR 0.78, 95% CI 0.61–0.98, p=0.037) were detected as significant factors by multivariate analysis. (table 1)

Abstract THU0181 – Table 1. Risk factors for developing sarcopenia in patients with rheumatoid arthritis

	Univariate		Multivariate		
	R value	p value	Odds ratio	95% CI	P value
GC Dosage >2 mg/day	0.217 -	0.035 -	- 8.0	- 1.2–54.8	- 0.034
Body fat mass	−0.211	0.040	0.78	0.61–0.98	0.037
ΔCRP	−0.205	0.046	-	-	-

GC: glucocorticoids, CI: confidence interval, Δ: change from baseline to 1 year
Conclusions: RA patients using GC at >2 mg/day or with low fat mass were more likely to develop sarcopenia.

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Rheumatoid arthritis – biological DMARDs

THU0182 A COMPARATIVE CLINICAL STUDY OF PF-06410293, A CANDIDATE ADALIMUMAB BIOSIMILAR, AND REFERENCE ADALIMUMAB FOR THE TREATMENT OF ACTIVE RHEUMATOID ARTHRITIS

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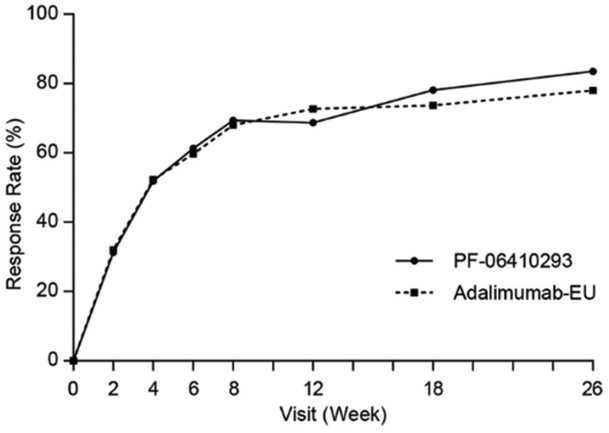
Background: To confirm the efficacy, safety and immunogenicity of biosimilars, a comparative clinical study is typically required.

Objectives: This double-blind, randomised, 78 week (wk) study compared the efficacy, safety and immunogenicity of PF–06410293, a candidate adalimumab biosimilar, with reference adalimumab sourced from the EU (ADA–EU), in biologic-naïve patients (pts) with active rheumatoid arthritis (RA) despite methotrexate (MTX; 10–25 mg/wk).
Methods: Pts with active RA (n=597) were stratified by region and randomised (1:1) to PF–06410293 or ADA-EU (40 mg subcutaneous injection every 2 wks), with continued MTX. The primary endpoint was American College of Rheumatology 20% improvement (ACR20) at Wk 12. Therapeutic equivalence was concluded if the 2–sided 95% confidence interval (CI) for the difference in Wk 12 ACR20 between arms was within the symmetric equivalence margin of ±14%. Additionally, a 2–sided 90% CI was requested by the US Food and Drug Administration, using the asymmetric equivalence margin of −12% to +15%. Secondary efficacy endpoints to Wk 26 included ACR20/50/70, change from baseline Disease Activity Score in 28 joints [DAS28(CRP)], European League Against Rheumatism (EULAR) response, achievement of DAS28(CRP) <2.6, and ACR/EULAR remission. QuantiFERON-TB testing was performed at Screening and Wk 26.
Results: Pts (78.7% female, 81.6% seropositive) had a mean age of 52.5 years, and mean RA duration of 6.8 years. Mean baseline DAS28(CRP) was 5.9 (PF–06410293) and 6.1 (ADA–EU). The observed Wk 12 ACR20 was 68.7% (PF–06410293) and 72.7% (ADA–EU) in the intent-to-treat population (figure 1). Using non-responder imputation (n=19; 3.2%), the treatment difference in Wk 12 ACR20 was −2.98%, and the corresponding CIs [95% CI (−10.38%,+4.44%); 90% CI (−9.25%,+3.28%)] were entirely contained within both equivalence margins (symmetric and asymmetric). The ACR20 difference ranged from −3.98% to +5.50% (Wks 2–26). Mean DAS28(CRP) change from baseline at Wk 26 was −2.7 and −2.8 in the PF–06410293 and ADA–EU arms, respectively. ACR50/70, EULAR response, DAS28(CRP) <2.6 and ACR/EULAR remission were similar between arms at each visit. Incidence of treatment–emergent adverse events (AEs) was 48.1% vs 47.8%, serious AEs were 4.0% vs 4.3% (with a fatal myocardial infarction in the ADA–EU arm) and serious infections were 0.7% vs 1.3% for PF–06410293 and ADA–EU, respectively. Injection site reactions occurred at 1.7% vs 2.0%, hypersensitivity events at 4.4% vs 8.4%, pneumonia at 0.7% vs 2.0%, and latent tuberculosis (based on specialist consultation for Wk 26 QuantiFERON-TB +) at 1.7% vs 0.3% for PF–06410293 and ADA–EU, respectively. Post–dose anti–drug antibody rates to Wk 26 were 44.4% (PF–06410293) and 50.5% (ADA–EU).



ACR=American College of Rheumatology; ITT=Intent-to-treat.

Figure 1. ACR20 response rates (ITT population)

Conclusions: The efficacy, safety and immunogenicity of PF–06410293 and ADA–EU were similar up to Wk 26 in pts with active RA on MTX. At Wk 26, pts on ADA-EU were blindly re-randomised (1:1) to continue ADA-EU or transition to PF-06410293 for ongoing treatment in the study.
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