In the STD group, 14 hospital admissions occurred, while in the TAP group there were 7 admissions ($p=0.128$). The corresponding figures for hospital admission due to infectious diseases were 6 in the STD group and 0 in the TAP group ($p=0.026$).

Conclusion: Tapering bDMARDs in RA patients in R/LDA is associated with fewer hospital admissions, with a possible protective effect especially toward infections.

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AB0284 RHEUMATOID ARTHRITIS REFRACTORY TO BIOLOGICAL TREATMENT

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Background: In Rheumatoid arthritis (RA), between 20% and 40% of patients do not achieve a 20% improvement in American College of Rheumatology (ACR) criteria, another similar percentage loses response over time or experience adverse events that forces them to the suspension of treatment. Those patients who have failed one or more therapeutic strategies, are more refractory patients and the response to successive targets is usually lower than naive patients, with 50% ACR20 response percentages.

Objectives: To describe the clinical-analytical characteristics and response to the last treatment, in rheumatoid arthritis (RA) refractory to biological disease modifying anti-rheumatic drugs (bDMARDs) and targeted synthetic DMARDs (tsDMARDs). To identify possible factors related to refractoriness to bDMARDs and tsDMARDs.

Methods: Retrospective multicentre, controlled study of patients with RA refractory to bDMARDs and tsDMARDs. Control group was formed by patients with non-refractory RA; matched by gender, age and diseaseduration. Refractoriness was defined as failure to more than 2 different targets of bDMARDs or tsDMARDs. Demographic, clinical-analytical data and rates of disease activity and physical function were collected. A descriptive analysis, a bivariate analysis and a binary logistic regression were performed to see the variables associated with refractoriness.

Results: A total of 94 patients were selected from HRUM and HCUVV: 47 with refractory RA and 47 with non-refractory RA. The clinical-epidemiological characteristics of both groups are classified in Table 1. The majority were women with a mean age of 57 years. There was a greater proportion of patients with multimorbidity and cardiovascular risk factors among the refractory to FAMEb. All patients affected a significant improvement with the new treatment in activity and physical function at 6 months compared to baseline. Refractoriness is associated with a higher body mass index [OR(IC95%), 7.73 (1.56-8.42); $p=0.012$], and depression [OR(IC95%), 1.11 (1.24-1.83); $p=0.035$].

Table 1. Clinical-epidemiological characteristics of patients.

Variable	Refractory RA (N=47)	Non-refractory RA (N=47)	p-value
Sex (female), n (%)	38 (80,9)	38 (80,9)	1,000
Age, means (SD)	57,1 (10,8)	57,4 (10,8)	0,896
Caucasian race, n (%)	45 (95,7)	44 (93,6)	0,646
Body mass index, means (SD)	30,4 (6,8)	26,5 (3,8)	0,002
Non-smoker, n (%)	26 (55,3)	28 (59,6)	
Former smoker>6 months, n (%)	16 (34,0)	7 (14,9)	
Smoker, n (%)	5 (10,6)	12 (25,5)	
Rheumatoid Factor, n (%)	40 (85,1)	42 (89,4)	0,536
Anti-cyclic citrullinated peptide, n (%)	37 (78,7)	38 (80,9)	0,797
Erosions, n (%)	33 (70,2)	28 (59,6)	0,280
Hypertension, n (%)	24 (51,1)	20 (42,6)	0,408
Obesity, n (%)	19 (40,4)	9 (19,1)	0,024
Diabetes Mellitus, n (%)	10 (21,3)	6 (12,8)	0,272
Dyslipidemia, n (%)	20 (42,6)	15 (31,9)	0,286
Neoplasia, n (%)	2 (4,3)	0 (0,0)	0,153
Fibromyalgia, n (%)	4 (8,5)	1 (2,1)	0,168
Depression, n (%)	18 (38,3)	4 (8,5)	0,001
Multimorbidity, n (%)	17 (36,2)	6 (12,8)	0,008
Comorbidities number, median (IQR)	2,0 (1,0-3,0)	1,0 (0,0-2,0)	0,002

Conclusion: Patients with refractory RA have an adequate response to subsequent treatment lines. These patients have a remarkable percentage of associated comorbidities.

Disclosure of Interests: None declared

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AB0285 RANDOMIZED, OPEN-LABEL, SINGLE-DOSE, PARALLEL-GROUP PHARMACOKINETIC STUDY OF PF-06410293, AN ADALIMUMAB BIOSIMILAR, BY SUBCUTANEOUS DOSING USING A PREFILLED SYRINGE OR A PREFILLED PEN IN HEALTHY SUBJECTS

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Background: Similarity in efficacy, safety, and immunogenicity (IMG) of PF-06410293 (ADL-PF), an adalimumab (ADL) biosimilar, and reference ADL sourced from the European Union (ADL-EU), by subcutaneous (SC) injection using a prefilled syringe (PFS), have been demonstrated in a randomised controlled trial in patients with rheumatoid arthritis (RA) (NCT02480153).

Objectives: To determine if the pharmacokinetics (PK), safety and tolerability of ADL-PF were similar following a single SC dose by prefilled pen (PFP) or PFS in healthy subjects (NCT02572245).

Methods: In this phase 1, 2-arm study, healthy subjects, aged 18–55 years, were randomised (1:1) to receive ADL-PF (40 mg, SC) in the lower abdomen or upper anterior thigh by PFS or PFP. Primary endpoints were maximum observed serum concentration (C_{max}) and area under the serum concentration–time profile from time 0–2 weeks after dosing (AUC_{0-2wk}). Safety, including injection-site reactions (ISRs), and secondary PK endpoints, were also assessed. Bioequivalence between ADL-PF administered by PFS or PFP device was demonstrated if the 90% confidence intervals (CIs) for the test/reference ratios of AUC_{0-2wk} and C_{max} fell within the 80.00–125.00% pre-specified margin.

Results: A total of 164 subjects, stratified by body weight were randomised and assigned to treatment; ADL-PF PFS (n=81) and PFP (n=83). Baseline characteristics were comparable between treatment arms. 163 subjects were included in the primary PK analysis. The concentration–time profiles were comparable between the ADL-PF PFS and PFP treatment arms, and were characterized by an increase in serum drug concentrations, with the C_{max} achieved at approximately 6–7 days, followed by a multi-phasic decline in drug concentrations. The 90% CIs for test/reference ratios of the geometric means for the primary PK parameters fell within the pre-specified margin (Table). In total, 50 and 51 treatment-emergent adverse events (AEs) were reported in 31 (38.3%) and 29 subjects (34.9%), respectively, in the ADL-PF PFS and PFP groups. One subject experienced an unrelated serious AE in the ADL-PF PFS group. Injection-site pain was similar between treatment arms at all time points, and for the 2 injection-site locations. IMG testing was limited to subjects experiencing an ISR and/or rash AE, and a matched control group, with 11 (11/15; 73.3%) and 7 (7/15; 46.7%) subjects, respectively, testing anti-drug