Abstract AB0269 – Table 2. Ankle and knee involvement in remission

	DAS28<2.6. 417 patients in total	DAS28<2.6. RF pos, anti- MCV pos: 131 patients	DAS28<2.6. RF neg, anti- MCV neg: 120 patients
Right knee synovitis	1,43%	2,29%	0
Left knee synovitis	0,95%	1,52%	0
Both knees synovitis	0	0	0
% of patients with knee involvement	2,39%	3,87%	0
Right ankle synovitis	6,71%	6,87%	6,66%
Left ankle synovitis	7,19%	7,63%	8,33%
Both ankles synovitis	0,23%	0,76%	0
% of patients with ankle involvement	13,66%	13,74%	15%

Conclusions: Our present data show that ankle synovitis is rather common in patients with serologically and clinically different forms of RA and highlight the importance of careful medical examination, even in case of clinical remission.

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AB0270

TREATMENT RESPONSE TO RITUXIMAB IN COMBINATION WITH LEFLUNOMIDE IS INFLUENCED BY ANTICCP STATUS IN ACTIVE RHEUMATOID ARTHRITIS: RESULTS FROM A MULTICENTER RANDOMISED PLACEBO-CONTROLLED INVESTIGATOR INITIATED CLINICAL TRIAL IN ACTIVE RHEUMATOID ARTHRITIS (AMARA-STUDY)

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Background: Use of biologicals such as Rituximab (RTX) in Rheumatoid Arthritis (RA) is effective and often only licensed in combination with Methotrexate (MTX). In cases of contraindications to or intolerances, other cDMARDs are frequently used in routine care without data from RCTs. Patients with positive antiCCP-status were identified in previous studies to better respond to RTX in combination with MTX.

Objectives: Here we present for the first-time data of the impact of antiCCP status on ACR response in the combinational therapy of RTX and Leflunomide (LEF).

Methods: A total of 189 patients with active RA (DAS28 >3.2 and at least 3 SJC and 3 TJC) despite stable LEF treatment were screened for a 52 weeks double-blind placebo controlled multicenter RCT. Patients were randomised to receive either two times 1000 mg RTX i.v. or PLA, followed by a second course of RTX of either two times 500 or 1000 mg at week 24. The primary endpoint of the study was superiority of RTX in ACR20 and 50 responses during 24 weeks treatment period. Adult patients who had inadequate response to more than one antiTNF or failed more than three cDMARDs were excluded. Disease activity was measured at each visit and compared according to antiCCP status. For safety evaluation, frequency and severity of adverse events were documented.

Results: Of 189 screened patients 148 were randomised. The mean age was 56 years; the mean body weight 76 kg and 74% were female. The disease activity (DAS28) at baseline was 5.57 for RTX and 5.54 for PLA. 57.1% of the patients were antiCCP-positive for RTX compared to 59.6% for PLA. In the RTX group, antiCCP-positive patients' disease duration was 8.8 years compared to 5.6 years in the antiCCP-negative group, DAS28 was 5.73 vs. 5.32 and CRP levels were

11.1 mg/L vs. 5.3 mg/L. RTX demonstrated significant superiority compared to PLA at week 16 in both, ACR 20 and ACR 50 response. AntiCCP-positive patients showed a higher probability to respond to the RTX/LEF treatment than antiCCP-negative patients (figure 1). 43 serious adverse events were reported, 27 of them in the RTX treatment group during the placebo-controlled period.

Abstract AB0270 – Figure 1

Conclusions: Here we report data of the first RCT investigating the combination of RTX with LEF in RA. The treatment with RTX in combination with LEF demonstrated significant efficacy compared to PLA for ACR20 and 50 responses with highest response level at week 16. AntiCCP-positive patients showed a higher probability for treatment response compared to antiCCP-negative ones. The combination of RTX and LEF demonstrated a reasonable safety profile.

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AB0271

RS12218 POLYMORPHISM IN SAA1 GENE IN THE RUSSIAN POPULATION OF RA PATIENTS IS ASSOCIATED WITH SECONDARY AMYLOIDOSIS. A PILOT STUDY

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Background: Secondary amyloidosis (SA) is a serious complication of rheumatoid arthritis (RA), which is often fatal. Identification of associated risk factors, including genetic ones, is an important task.

Objectives: To assess the role of SAA1 gene polymorphism, encoding serum amyloid-A, as a risk factor predisposing to SA in the sample of Russian RA patients.

Methods: The study included 60 patients with RA, fulfilled the American College of rheumatology criteria (ACR) 1987. Of these 35 (mean age 49.5±10.8 y, mean disease duration 18.5±8.9) developed SA manifestations, confirmed histologically: group SA (+). 25 patients (mean age 56.7±11.7 y, mean disease duration 16.3±7.5 y) did not have either clinical or histological SA signs: group SA (-). The control group (C) consisted of 65 healthy employees. SAA1 gene polymorphism rs12218 (-13 T/C), mapped in the 5' flanking region of the gene, was studied in 125 subjects by polymerase chain reaction in real time (RT-PCR) with subsequent melting curves analysis.

Results: Statistically significant differences in the rates of TT, TC and CC genotypes of rs12218 polymorphism were established between SA(+) group and the controls (17.1%, 64.0%, 48.6% and 38.5%, 46.1%, 15.4%, respectively, p=0.029). High rate (58.6%) of the mutant C allele in SA(+) group compared to the control group (38.5%) predetermines high risk of susceptibility to SA in RA patients [OR 2.26, 95% CI(1.20–4.28), p=0.010]. Significant differences in rs12218 polymorphism rates were found between SA(+) and SA(-) groups [p<0.001]. The frequency of TC + CC genotype was significantly higher in the SA (+) group compared to SA(-) group [82.9% vs 36.0%, p<0.001]. The risk of predisposition to SA development among RA patients was increased when C allele frequencies in the group with SA (58.6%) were compared with the group without SA (22.0%) [OR 5.01, 95% CI (2.07–12.58), p<0.001]. No significant differences were found in the frequencies of genotypes and rs12218 alleles between SA(-) pts and the controls (p>0.05).