Conclusions: Serum capacity to activate PAD4 was associated with ACPA and RF positivity in patients with early RA, but no distinct relationship was seen for Disease Activity Score.

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FRI0026

U-ACT-EARLY TRIAL 3 YEARS FOLLOW-UP. THE LONGER EFFECTIVENESS OF TREAT-TO-TARGET STRATEGIES IN EARLY RA WITH TOCILIZUMAB, METHOTREXATE, OR THEIR COMBINATION

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Background: The U-Act-Early trial was a 2 year placebo controlled, double-blind randomised controlled trial in early (DMARD-naïve) RA patients treated to the target of sustained remission (SR), starting with tocilizumab (TCZ), methotrexate (MTX) or their combination (TCZ +MTX)¹. When the treatment target was achieved, medication was tapered and stopped, if patients remained in remission. During the trial period, the strategies starting with TCZ were more effective than the strategy initiating MTX only. Subsequently, patients were followed for 3 years, during which treatment was open and according to usual care.

Objectives: To establish the effectiveness of step-up strategies starting with MTX, TCZ or their combination in early RA over a 5 year period.

Methods: 226 of the 317 patients starting in the U-Act-Early trial (initial strategy: 75 TCZ +MTX, 79 TCZ, 72 MTX) participated in the 3 year follow-up phase. DAS28 was collected every 3 months during the first year and every 6 months thereafter.

The primary endpoint, was SR, defined as DAS28 <2.6 AND 28 joint count ≤4 for >24 weeks. Secondary endpoints were sustained drug free remission (sDFR), defined as remission for ≥3 months after tapering and stopping all medication during SR, and DAS28 over 5 years.

Differences between the randomised strategies in proportions of patients achieving SR and sDFR and durations of SR and sDFR were tested with Cochran-Mantel-Haenszel and Kruskal-Wallis tests, respectively.

A mixed model analysis was used to compare DAS28 over time, with a random intercept and fixed effects for: treatment, visit-week, the interaction visit-week* treatment, and it was corrected for gender, age, and for DAS28, RA-duration, CRP and RF-positivity at baseline.

Results: Baseline characteristics at the start of U-Act-Early of the patients included in this 3 year follow-up study were not significantly different from those of all patients included in U-Act-Early trial. Over 5 years, SR was achieved in 224/226 (99%) patients without significant differences (p=0.15) between the initial treatment strategies in proportions of patients achieving it, nor in durations (p=0.96) of these endpoints (table 1). Neither between-group significant differences were found for sDFR (proportion; p=0.10, duration; p=0.27), only a tendency for longer duration in TCZ +MTX. The mean DAS28 over 5 years was not significantly different between initial strategy groups (figure 1), but it was on average 0.15 (95% CI -0.12 to 0.42) units higher in the TCZ(+MTX) groups, compared to MTX initiation group.

Abstract FRI0026 – Table 1. Outcome for sustained (drug free) remission over 5 years

	Initial treatment strategy group			p-value
	TCZ+MTX	TCZ+placebo	MTX+placebo	
Sustained remission				
Proportion achieving, n/N (%)	75/75 (100)	77/79 (97.5)	72/72 (100)	0.15 ¹
Duration weeks, Median (IQR)	49 (37 - 81)	52 (40 - 71)	46 (36 - 114)	0.96 ²
Sustained drug free remission				
Proportion achieving, n/N (%)	26/75 (34.7)	19/79 (24.1)	14/72 (19.4)	0.10 ¹
Duration weeks, Median (IQR)	106 (72 - 157)	83 (31 - 156)	71 (30 - 147)	0.27 ²

¹= Cochran-Mantel-Haenszel test, ²=Kruskal-Wallis test

Abstract FRI0026 – Figure 1. DAS28 over time stratified for initial treatment strategy

Conclusions: On the short term, initiation of TCZ-based strategies yields the most benefit, but on longer term, no difference in important clinical outcomes was found anymore between initial strategy groups, probably due to continuation of the treat-to-target principle². Almost all patients achieved SR over 5 years, with a tendency for longer duration of sDFR in the TCZ+MTX strategy.

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FRI0027

PATIENT-BASED DISEASE ACTIVITY SCORE PREDICTS FLARE BETTER THAN IMPROVEMENT – BLOOD TEST PROVIDES INSIGNIFICANT CONTRIBUTION

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Background: Patient-derived Disease Activity Score (PDAS) was developed to allow rheumatoid arthritis (RA) patients to self-assess without the need of evaluator. Two versions, PDAS1 with ESR (erythrocyte sedimentation rate) and PDAS2 without, had been validated and shown to correlate well with DAS28 and display responsiveness to change in patients put on disease-modifying drugs. PDAS has the potential to inform disease activity change between evaluator's assessments and/or blood tests. This would be a useful monitoring tool to deliver treat-to-target tight RA control.

PDAS1=0.019×(PGA out of 100)+0.842×ln(ESR +2)+0.432×ln(patient 50 TJC +2)+0.271×HAQ