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

PDAS2= $2.667+0.021 \times (\text{PGA out of } 100)+0.483 \times \text{HAQ} +0.033 \times (\text{patient } 28 \text{ SJC}) +0.002 \times (\text{EMS in minutes})$ whereas PGA=patient global assessment, TJC=tender joint count; SJC=swollen joint count; HAQ=Health Assessment Questionnaire; EMS=early morning stiffness

Objectives: To assess whether PDAS is sensitive to change for an evaluator-based flare and improvement and whether PDAS1 (with ESR) is better than PDAS2.

Methods: A prospective cohort of 92 RA patients completed PDAS1 and 2 scores at the first and second clinic visits in a tertiary referral rheumatology centre. **Flare** was taken as increased RA activity from Simplified Disease Activity Index (SDAI) (remission or low activity) at the 1st visit → (moderate or high activity) at the 2nd visit, while **improvement** was the reverse change. Overall changes (Δ) of SDAI and PDAS1 and 2, in both directions, between these two visits were correlated using Spearman correlation coefficients. Further subgroup analysis (flare and improvement) was done by comparing the magnitude of changes between SDAI and PDAS1 and 2 using Mann-Whitney U test.

Results: Mean age of the cohort was 60 years, mean RA duration 14 years, 90% female, 71% sero-positive, 64% in remission/low disease activity at the 1st visit and follow-up interval was 17.5 weeks (standard deviation 9.4 weeks). At the 2nd visit, 11 out of 59 patients had a flare while 10 out of 33 patients improved. The Spearman correlation coefficients of Δ SDAI with Δ PDAS1 and Δ PDAS2 were 0.55 and 0.54 respectively (both $p \leq 0.001$). Data distributions were depicted in the scatterplot.

For the subgroup of flare, both Δ PDAS1 and 2 were significantly associated with the corresponding Δ SDAI (all $p < 0.02$). However, this association was not significant in the subgroup of improvement (See table 1). PDAS1 did not appear to perform better than PDAS2 in both groups of flare and improvement.

Abstract FRI0027 – Table 1

Flare (n=59)			
	Flare (11/59)	No flare (48/59)	P-value
Δ SDAI	+6.90 (8.20)	0.12 (0.16)	<0.001
Δ PDAS1	+0.75 (1.40)	0.01 (0.59)	0.016
Δ PDAS2	+0.52 (0.74)	0.00 (0.32)	<0.001
Improvement (n=33)			
	Improved (10/33)	Not improved (23/33)	P-value
Δ SDAI	-6.80 (7.20)	0.40 (6.90)	<0.001
Δ PDAS1	-1.40 (0.96)	0.06 (0.49)	0.20
Δ PDAS2	-0.16 (0.35)	0.00 (0.54)	0.25

Values are median (interquartile range). P-values are results of Mann-Whitney U test.

Conclusions: Overall PDAS1 and 2 are sensitive to change, but both predicted flare better than improvement. Clinically signalling flare has a far greater utility than documenting improvement. PDAS2 was as sensitive as PDAS1 in predicting flare yet without the need of a blood test for ESR. Hence, PDAS2 is suitable to serve as a purely patient-based home monitoring tool to detect a flare.

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FRI0028

DEVELOPMENT AND IMPLEMENTATION OF AN EDUCATIONAL VIDEO THAT INSTRUCTS PATIENTS WITH RHEUMATOID ARTHRITIS FOR SELF-ASSESSMENT OF DISEASE ACTIVITY: METHODOLOGY OF THE AUTO-DAS IN MIDDLE EASTERN ARAB COUNTRIES STUDY

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Background: Using a treatment target in rheumatoid arthritis (RA), such as DAS-28 and involving patients in their disease management can improve prognosis.

Objectives: To develop and implement an educational video that instructs patients with RA for self-assessment of disease activity using DAS-28.

Methods : *Step 1:Initiation.* Rheumatologists from some Middle Eastern Arab countries were invited to participate in this study. International experts and societies were contacted to access pre-existing educational material.

Step 2: Development. Different material sources were synthesized and translated into Arabic and validated by the rheumatologists. The educational video was shot by a professional team with a real patient and a rheumatologist on set.

Step 3. Validation. The final products (leaflets and video) were validated by the rheumatologists and tested with patients (figure 1). Obstacles were noted at the various study levels.

Results: 23 rheumatologists from 7 Middle Eastern Arab countries participated in the study. A one-page educational leaflet was developed in Arabic and English languages. An educational video presenting the treat-to-target concept and the basics of DAS performance was produced in Arabic language with English subtitles. Obstacles at the rheumatologist, patient, cultural and logistic levels were identified and the potential solutions were addressed by the study team.

Abstract FRI0028 – Table 1

Rheumatologist	Patient	Cultural	Logistics
DAS as target	Patient empowerment	Uniform text	Multiple IRB
Patient empowerment	Video understanding	Acceptable video	Funding
Patient adherence	Confidence in performance	Cultural mix	Computerised data

Conclusions: Collaboration between several countries sharing the same language and similar cultural backgrounds was possible and able to produce an