injections of TCZ monotherapy or in combination with csDMARDs up to 24 weeks. From week 16 onwards dose reduction and/or discontinuation of glucocorticoids (GC) and NSAIDs was allowed. Primary endpoints were occurrence of adverse events (AEs), serious AEs (SAEs) and AEs of special interest (AESI). Secondary endpoints were time to GC/NSAID dose reduction and/or discontinuation, and DAS28 (remission), ACR 50 response, EULAR response, SDAI, CDAI and HAQ-DI. Occurrence of AEs was analysed using descriptive statistics. Changes over time in efficacy endpoints and response rates were analysed using Wilcoxon test.

Results: Of the 150 patients 121 (81%) patients completed the treatment period. In 91% of the patients there was ≥ 1 AE, in 9% an SAE, and in 4% an AESI. Most AEs were mild or moderate in intensity and resolved without sequelae. Permanent TCZ treatment discontinuations due to AEs occurred in 7% of the 150 patients; of these, five patients were prematurely withdrawn from the study due to AEs. From week 16 onwards, 8 (5.3%) and 13 (8.7%) patients discontinued or reduced (for any reason) the dose of NSAIDs or GCs, respectively. Between weeks 16 and 20, 2 (1.3%) patients discontinued or reduced the dose of NSAIDs due to safety and other reasons. The dose of GCs was discontinued or reduced in 3 patients (2.0%) between weeks 16 and 20, and in another 3 between weeks 20 and 24 (2.0%), in all 6 patients mainly due to safety reasons (1.3%), while NSAIDs dosage remained stable. The safety profile observed in this trial was in line with the known TCZ safety profile. Efficacy parameters improved over time for all of the endpoints. A selection of these results is shown in table 1.

Abstract THU0210 – Table 1. Efficacy results

Table. Efficacy results.

Efficacy parameter		P-value
Change from BL in DAS28, median (min, max)		P<0.0001
Week 4	1.9 (1.10, -4.54)	
Week 12	-3.0 (0.89, -6.00)	
Week 24	3.2 (-0.06, -7.57)	
DAS28 remission, % (n/N)		
Week 4	52.1 (75/144)	
Week 12	77.4 (103/133)	
Week 24	86.8 (105/121)	
ACR 50 response rate, %		P<0.0001
Week 4	21.5	
Week 12	45.1	
Week 24	66.1	
EULAR good response, % (n/N)		P<0.0001
Week 4	59.7 (86/144)	
Week 12	85.0 (113/133)	
Week 24	85.0 (113/133)	
Change from BL in SDAI, median (min, max)		P<0.0001
Week 4	-11.0 (-30.9,8.2)	
Week 12	17.1 (-46.5,16.9)	
Week 24	-19.7 (-53.3,-0.07)	
Change from BL in CDAI, median (min, max)		P<0.0001
Week 4	-9.1 (-30.8,8.3)	
Week 12	-15.1 (-45.16,9)	
Week 24	17.3 (-60.2,0.1)	
Change from BL in HAQ-DI, median (min, max)		P<0.0001
Week 4	-0.25 (-1.25,1.13)	
Week 12	-0.38 (-2.13,0.38)	
Week 24	-0.50 (-2.38,0.88)	

DAS28: disease activity score of 28 joints; ACR: American College of Rheumatology; EULAR: European League Against Rheumatism ;BL: baseline; SDAI: simple disease activity index; CDAI: clinical disease activity index; HAQ-DI: health assessment questionnaire disease activity. P-values refer to the differences between baseline and week 4, week 12 and week 24 measured per parameter.

The median time of follow-up of the studied population was 822 days, IQR 429–727 days.

Conclusions: The OSCAR study showed that SC TCZ is safe, well-tolerated and effective in RA patients with an inadequate response to csDMARDs and max 1 bDMARD. Importantly, a subset of patients could reduce GC and/or NSAID use during SC TCZ treatment. These findings support the notion that SC TCZ can be safely used in clinical practice.

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SIX MONTHS AFTER TREATMENT DISCONTINUATION TNF IS STILL IN COMPLEX WITH ADALIMUMAB

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Background: Many patients with rheumatoid arthritis (RA) are successfully treated with tumour necrosis factor inhibitors (TNFi). We recently developed a novel assay that can quantify TNF in the presence of large amounts of TNFi, i.e. a 'drug-tolerant' assay. We showed in RA patients that TNF levels increased and stabilised during adalimumab treatment due to complex forming between TNF and adalimumab. In the presence of adalimumab, all TNF was in complex and biologically inactive. Once in remission, some patients can discontinue the TNFi for a prolonged period. It is unclear how long adalimumab levels are detectable and TNF complexes are formed after the last adalimumab administration.

Objectives: To investigate adalimumab levels and complexed TNF levels 6 months after the last adalimumab administration.

Methods: TNF and adalimumab levels were measured using a novel drug-tolerant competition enzyme-linked immunosorbent assay (ELISA), and a regular ELISA, respectively, in 11 consecutive RA patients with stable low disease activity (disease activity score of 28 joints<3.2) who discontinued adalimumab for 6 months (prior dose: 40 mg every 2 weeks). Blood samples were drawn prior to adalimumab discontinuation and 3 and 6 months thereafter.

Results: After the last adalimumab administration, mean adalimumab level decreased from 5.5 (SD 2.9) to 0.55 (0.52) and 0.11 (0.13) µg/mL at 3 and 6 months after treatment discontinuation, respectively (figure 1A). In contrast, complexed TNF levels remained stable for prolonged periods of time: in 8 patients TNF levels at 3 months were indistinguishable from levels seen at baseline, on standard-dose adalimumab (figure 1B). After 6 months, TNF still remained stable in patients with adalimumab concentrations above 0.1 µg/mL (n=4). Overall, mean TNF levels decreased from median 381 (inner quartiles 16; 707) to 290²; 755 and 83²; 532 pg/mL at 3 and 6 months after treatment discontinuation, respectively. In 5 patients, TNF levels decreased significantly. In those patients, adalimumab levels dropped to, or below the detection limit.

Conclusions: This is the first study showing that TNF is still in complex with adalimumab in the majority of patients 6 months after the last administration. Therefore, one may wonder at which point in time a patient has truly discontinued adalimumab treatment.

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