case series even lower doses might be sufficient for maintenance treatment, potentially improving safety and decreasing costs.(1)

Objectives: To compare effectiveness of RTX retreatment with ultra-low doses ($1 \times 500\text{mg}$ or $1 \times 200\text{mg}$) to standard low dose ($1 \times 1000\text{mg}$).

Methods: A 6-month double-blind randomised controlled non-inferiority trial (REDO study (2)) was performed in 5 centres in the Netherlands. Patients with RA responding well to RTX (based on DAS28-CRP <2.9 or clinical judgement) were randomised (1:2:2) to $1 \times 1000\text{mg}$, $1 \times 500\text{mg}$ or $1 \times 200\text{mg}$ RTX respectively. DAS28-CRP and peripheral CD19+ B-cells were measured at baseline, 3 and 6 months. Primary analysis (per protocol with LOCF) consisted of a hierarchical testing procedure comparing ultra-low doses ($1 \times 500\text{mg}$ at 3 and 6 months, then $1 \times 200\text{mg}$ at 3 and 6 months) to $1 \times 1000\text{mg}$ using a non-inferiority margin of 0.6 (on DAS28-CRP). DAS28-CRP change of study groups was compared using linear regression, adjusted for baseline DAS28-CRP, RF/ACPA status and concomitant csDMARD use.

Results: The projected inclusion was met ($n=142$, table 1a). In both ultra-low dose groups 2 patients received an extra dose of 1000mg RTX due to a flare. The 500mg dose was non-inferior to 1000mg at 3 months (-0.04 (95% CI -0.39 to 0.30)), but not at 6 months (0.31 (95% CI -0.05 to 0.68)). The 200mg dose was non-inferior to 1000mg at both time points. Because of our pre-defined hierarchical testing, non-inferiority could not formally be inferred for the 200mg dose. Mean DAS28-CRP scores remained low in all groups throughout the study, and B-cell counts decreased similarly at 3 months (figure 1). In the 200mg group, more patients received intramuscular corticosteroid injection(s) compared to the

1a. Baseline characteristics (mean (sd) or n(%))			
	1000mg (n=29)	500mg (n=58)	200mg (n=55)
Age	63.8 (9.0)	64.0 (10.9)	64.2 (12.2)
Female	18 (62%)	37 (64%)	40 (73%)
Disease duration in years	17.1 (11.1)	14.9 (10.7)	13.5 (7.2)
RF/ACPA positive	27 (93%)	54 (93%)	49 (89%)
Concomitant csDMARD	18 (62%)	35 (60%)	32 (58%)
1b. Flares, co-medication and SAEs (n(%))			
Flare(s)	3 (10%)	14 (24%)	10 (18%)
Extra 1000mg RTX received*	0 (0%)	2 (3%)	2 (4%)
im gc injection(s)	4 (14%)	7 (12%)	16 (29%)
SAE(s)	3 (10%)	5 (9%)	5 (9%)

*2 patients with regular RTX accidentally given before study end (protocol violation) not included

1000mg group (table 1b).

Conclusion: Non-inferiority of retreatment with $1 \times 500\text{mg}$ or $1 \times 200\text{mg}$ rituximab versus $1 \times 1000\text{mg}$ after 6 months could not formally be established. However, ultra-low doses appear similarly effective in the majority of RA patients, judged by DAS28-CRP course over time and B-cell results, with use of slightly more co-medication.

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LB0011

A PHASE II SINGLE ARM (ADAPTIVE DESIGN) TRIAL OF TOCILIZUMAB IN ANTI-TNF REFRACTORY PATIENTS WITH JIA-ASSOCIATED UVEITIS (APTITUDE TRIAL)

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Background: Children with severe uveitis or those who have not responded to anti-tumour necrosis factor agents and methotrexate (MTX) are at significant risk of sight loss¹⁻³. Evidence on alternative therapies is needed.

Objectives: To evaluate the clinical response to Tocilizumab with MTX in children with Juvenile Idiopathic Arthritis (JIA)-associated uveitis who failed anti-TNF therapy to determine the need for further research.

Methods: Multi-centre, open label, single arm trial using a two-stage Simon design⁴.

Setting: 7 UK sites

Participants: Children aged 2-18 years with JIA-associated uveitis defined as "2 readings of cellular infiltrate in anterior chamber of SUN criteria grade $\leq 1+$ or more during the preceding 6 weeks, the latest reading must be at the time of screening." Intervention: Treatment with MTX and those weighing ≤ 30 kg treated with 162 mg of Tocilizumab every 2 weeks and those weighing <30 kg every 3 weeks.

Main Outcome Measures: Primary outcome was treatment response at 12 weeks defined as per SUN criteria as a 2 step decrease in the level of inflammation or decrease to 0 between baseline and 12 weeks of treatment. Data on safety, topical corticosteroid usage, tolerability, compliance, optic and ocular measurements, American College of Rheumatology Pediatric core set criteria measurements, changes in biologic/Disease-modifying anti-rheumatic drugs therapy and flares of arthritis collected.

Results: 22 participants were registered; 1 was removed as found to be ineligible soon after registration. A total of 7 were classified as a pre-specified treatment response, the median unbiased estimate of proportion was 34% 95% CI (25% to 57%), $p=0.11$. 4 had macular oedema at baseline and this was resolved in 3 participants. Post-hoc analysis showed that there were 4 (19%) who were classified as a non-treatment response but had at least a one-step improvement at 3 months, leaving 10 (48%) showing no response, the mean (SD) number of steroid drops at baseline was 4.48 (3.11) and which reduced to 4.33 (2.29) at 12 weeks. Safety results were consistent with the known safety profile of Tocilizumab; no SAEs were reported.

Conclusion: Whilst this study did not pass the pre-specified criterion, the data shows almost a half of the participants including 7 (33%) with a 2-step improvement, and a further 3 (14%) with 1-step improvement, responded to Tocilizumab.

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