therapy. Clinical response was assessed using the European League Rheumatism (EULAR) response criteria [2]. Serum etanercept levels were measured by sandwich ELISA based on the ability of etanercept to bind TNF. Antibodies against etanercept were measured by bridging ELISA (Promonitor).

Results: The 47 female and 11 male were of a mean age 52.1±11.2 years (22–87) and have been living with RA for a mean of 13.2±8.2 years (2–24). At baseline the DAS28-$_{ESR}$ mean score was 6.1±1.0. After six months of etanercept treatment, 20 (34.5%) patients were in remission, 20 (34.5%) were in low disease activity and 18 (31%) were in moderate disease activity. The serum etanercept levels were significantly higher in patients in remission compared with patients in moderate disease activity (p=0.05). According to the EULAR response criteria, RA patients were divided into responders (52pts, 89.7%) and non-responders (6 pts, 10.3%). Median etanercept levels in all patients were 3.937mcg/ml. There were no statistical differences in etanercept levels between responders and non-responders patients (p=0.41). In addition, we stratified all patients into quartiles according to height of the etanercept level. The percentage of EULAR good responders was significantly different between the highest and the lowest quartiles ($p<0.05$).

Anti-etanercept antibodies were not found in any of the studied patients (0/58).

Conclusions: Patients with RA who did not respond to etanercept treatment achieved lower etanercept levels compared with responding patients. Higher concentrations of the drug were associated with a better response to treatment. Further studies are needed to provide evidence for this approach.

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FRI0207 INDUCTION OF SUSTAINED REMISSION IN EARLY INFLAMMATORY ARTHRITIS WITH THE COMBINATION OF INFLIXIMAB PLUS METHOTREXATE, METHOTREXATE ALONE OR PLACEBO: THE DINORA TRIAL

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Background: Rheumatoid arthritis is a chronic form of inflammatory arthritis that is thought to have an early stage or reversibility with effective therapy ("window of opportunity").

Objectives: In the present study, we explored the effects of induction therapy with anti-TNFα antibody infliximab (IFX) plus methotrexate (MTX) compared with MTX alone and with placebo (PL) in patients with very early inflammatory arthritis.

Methods: In an investigator-initiated, double-blind, randomized, placebo-controlled, multi-center trial, patients with synovitis of 12–16 weeks duration in at least 2 joints underwent one year of treatment with IFX in combination with MTX, MTX monotherapy or PL randomized in a 2:2:1 ratio. The primary endpoint was clinical remission after 1 year (sustained for at least two consecutive visits 8 weeks apart including week 54) with remission defined as no swollen joints, 0 - 2 tender joints and a C-reactive protein (CRP) level within the normal range (<0.5 mg/dl) or a normal ESR (<25 mm/h). Further, sustainability of remission was assessed during the second year of the study, during which patients received no treatment. The trial was registered at www.isrctn.com (ISRCTN21272423).

Results: See Table 1.

Table 1. Number of patients in clinical remission at 6 months, one year and two years

	1: IFX+MTX (N=38)	2: MTX (N=36)	3: PL (N=16)
6 Mo	10 (26%)	6 (17%)	0
1 Year*	12 (32%)	5 (14%)	0
2 Years*	9 (24%)	1 (3%)	3 (19%)

*$p<0.05$ across the three groups.

90 patients participated in the present study. At week 54 (primary endpoint), 32% of the patients in the IFX+MTX group achieved sustained remission compared with 14% on MTX alone and 0% on PL (Table). This difference was statistically significant for all three groups ($p<0.05$) and for IFX+MTX vs PL ($p<0.05$) separately, but not for IFX+MTX vs MTX (p=0.10), nor for MTX vs PL (p=0.31). Remission was maintained during the second year on no therapy in 75% of the IFX+MTX patients but was lost in 80% of the MTX-only-patients (Table). The analysis of radiographic progression did not reveal significant differences between the three treatment groups. The number needed to treat (NNT) to achieve one additional sustained remission at 52 weeks with IFX+MTX was 3 compared to placebo; the NNT for MTX alone versus placebo was 7 (NNT=6 for IFX+MTX vs MTX alone).

Conclusions: These results indicate that patients with early arthritis can benefit from induction therapy with anti-TNF plus MTX compared to MTX alone, suggesting the existence of a window of opportunity where intensive treatment can alter the disease evolution

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FRI0208 COMPARISON OF EFFICACY, SAFETY AND PHARMACOKINETICS OF INFLIXIMAB BIOSIMILAR (BCD-055) AND INNOVATOR INFLIXIMAB

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Background: Infliximab (IFX) was one of the first genetically engineered biologics successfully applied for medical use in patients with active RA and patients with AS. Previous preclinical studies showed that BCD-055 is highly similar to innovator IFX.