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DISEASE ACTIVITY ASSESSMENT USING THE DAS28, CDAI AND SDAI AND EFFECT OF ANTI-DRUG ANTIBODY ON CLINICAL RESPONSE IN A RANDOMIZED, DOUBLE-BLIND, COMPARATIVE TRIAL OF CT-P13 AND INNOVATOR INFIXIMAB: PLANETRA STUDY

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Background: CT-P13 is a biosimilar to innovator infliximab (INX) approved by the European Medicines Agency. From the PLANETRA, which is randomized, double-blind, active-controlled trial to assess efficacy and safety of CT-P13 in rheumatoid arthritis (RA) patients, therapeutic equivalence was demonstrated via the primary endpoint (ACR20 at Week30). Several secondary endpoints exist that can capture valuable information to the clinician.

Objectives: To compare efficacy via the DAS28, CDAI, and SDAI of CT-P13 and INX in patients with RA and effect of anti-drug antibody (ADA) on the clinical outcome measures.

Methods: In PLANETRA, 606 patients with RA were treated with either 3 mg/kg of CT-P13 or INX with methotrexate at usual schedule up to Week 54. Key secondary endpoints were CDAI, SDAI, and DAS28. ADA was measured at baseline and at Week 14, 30 and 54 by an electrochemiluminescent assay.

Results: The mean baseline DAS28 scores reflected high disease activity (DAS28-ESR, 6.7 vs 6.6; DAS28-CRP, 5.9 vs 5.8; CT-P13 vs INX). The mean change in DAS28-ESR over 54 weeks was -2.4 in both treatment groups. The baseline CDAI and SDAI scores were similar between treatment groups (mean CDAI, 40.7 vs 39.6; SDAI, 42.6 vs 41.4; CT-P13 vs INX, respectively). At week 54, CDAI decreased by -25.7 and -24.0 and SDAI decreased by -26.3 and -24.6 in the CT-P13 and INX groups, respectively. Statistically significant difference between groups was not shown in these assessments. The proportion of patients who become ADA positive was comparable between CT-P13 (52.3%) and INX (49.5%). More improvement on DAS28-ESR was shown in ADA negative subgroup than in ADA positive subgroup at Week 54, similarly in both treatment groups (CT-P13, -2.8 vs -2.1; INX, -2.7 vs -2.0). SDAI score decreased more in ADA negative subgroup than ADA positive subgroup up to Week 54 (CT-P13, -28.5 vs -24.3; INX, -26.7 vs -22.3). Similar trends were found in DAS28-CRP and CDAI at Week 54 (p<0.05). No statistical differences were shown between CT-P13 and INX within the both ADA subgroups in these efficacy outcomes at Week 54. DAS28-ESR or CRP results were not different between two treatment groups over time in each ADA subgroup (p>0.05), but different between ADA subgroups over time within each treatment group (p<0.05).

Conclusions: These results demonstrate the efficacy of CT-P13 which is comparable to that of INX, based on various clinical outcome measures. The ADA development could diminish the clinical response achieved by infliximab, and the magnitude of influence was similar in both CT-P13 and INX treatment groups throughout the study.


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