A Safety and Efficacy Comparison of Biosimilar CT-P10 and Innovator Rituximab in Patients with Rheumatoid Arthritis

NEWS
Pain Management

As per recent multinational, randomized, double-blind trial published in Mabs Journal, the rituximab (RTX) and its biosimilar CT-P10 appeared to have identical immunogenicity, pharmacodynamics, safety and efficacy measures in managing rheumatoid arthritis (RA). Park W and colleagues conducted the trial within 372 RA patients, out of which 161 patients allocated to CT-P10 group and 211 to RTX group. The change in primary efficacy endpoint from baseline to week 24 was measured through Disease Activity Score 28 (by using joints-C-reactive protein). The AUC from time zero to last measurable concentration, from time zero to infinity and maximum level after two infusions were used to measured co-primary pharmacokinetic endpoints. The safety, immunogenicity and pharmacodynamics were also determined.

The change in DAS28-CRP noticed from baseline to 24 weeks was -2.09 for RTX and -2.13 for CT-P10. The co-primary pharmacokinetic endpoints exhibit the equivalence margin of 80-125%. The estimated treatment difference between CT-P10 and RTX presented efficacy equivalence margin of ±0.5. The safety, immunogenicity and pharmacodynamics and pharmacokinetics profiles of both drugs were identical up to 24 weeks. The efficacy to control RA through CT-P10 and RTX was same as well. As per results RA management was equally controlled by CT-P10 and RTX.

Source: MAbs.

Link: https://www.ncbi.nlm.nih.gov/pubmed/30010481

The original title of article: Comparison of biosimilar CT-P10 and innovator rituximab in patients with rheumatoid arthritis: a randomized controlled Phase 3 trial.

Authors: Park W et al.

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