A randomized, placebo-controlled trial of infliximab plus methotrexate for the treatment of polyarticular-course juvenile rheumatoid arthritis

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Resumen

Objective. To evaluate the safety and efficacy of infliximab in the treatment of juvenile rheumatoid arthritis (JRA). Methods. This was an international, multicenter, randomized, placebo-controlled, double-blind study. One hundred twenty-two children with persistent polyarticular JRA despite prior methotrexate (MTX) therapy were randomized to receive infliximab or placebo for 14 weeks, after which all children received infliximab through week 44. Patients received MTX plus infliximab 3 mg/kg through week 44, or MTX plus placebo for 14 weeks followed by MTX plus infliximab 6 mg/kg through week 44. Results. Although a higher proportion of patients in the 3 mg/kg infliximab group than in the placebo group had achieved responses according to the American College of Rheumatology (ACR) Pediatric 30 (Pedi 30) criteria for improvement at week 14 (63.8% and 49.2%, respectively), the between-group difference in this primary efficacy end point was not statistically significant (P = 0.12). By week 16, after the crossover from placebo to infliximab 6 mg/kg when all patients were receiving infliximab, an ACR Pedi 30 response was achieved in 73.2% of all patients. By week 52, ACR Pedi 50 and ACR Pedi 70 responses had been reached in 69.6% and 51.8%, respectively, of patients. Infliximab was generally well tolerated, but the safety profile of infliximab 3 mg/kg appeared less favorable than that of infliximab 6 mg/kg, with more frequent occurrences of serious adverse events, infusion reactions, antibodies to infliximab, and newly induced antinuclear antibodies and antibodies to double-stranded DNA observed with the 3 mg/kg dose. Conclusion. While infliximab at 3 mg/kg and 6 mg/kg showed durable efficacy at 1 year, achievement of the primary efficacy end point at 3 months did not differ significantly between infliximab-treated and

placebo-treated patients. Safety data indicated that the 6-mg/kg dose may provide a more favorable risk/benefit profile. These results warrant further investigation in children with JRA.

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