Pediatric Rheumatology

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Oral presentation

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2.3 Long-term efficacy and safety of infliximab plus methotrexate for the treatment of polyarticular course juvenile rheumatoid arthritis (JRA): Findings from an open-label treatment extension

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from 15th Paediatric Rheumatology European Society (PreS) Congress
London, UK. 14–17 September 2008

Published: 15 September 2008

Pediatric Rheumatology 2008, **6**(Suppl 1):S3 doi:10.1186/1546-0096-6-S1-S3

This abstract is available from: http://www.ped-rheum.com/content/6/S1/S3

We report long-term safety & efficacy of infliximab (IFX)+ methotrexate (MTX) treatment in JRA patients. In an international, multicenter, randomized, double-blind study, 122 children w/active polyarticular JRA despite prior MTX therapy received MTX plus a 3-dose induction (wks 0, 2, 6) of IFX 3 mg/kg through wk 44, or placebo (PBO) for 14 wks followed by IFX 6 mg/kg (wks 14, 16, 20, & then q8 wks) through wk 44. Patients completing treatment through wk 44 were eligible to enter an open-label extension (OLE) of IFX 3 mg/kg, beginning at wk 52 & continuing q8 wks through wk 196. All patients continued with concomitant MTX. Physicians could increase or decrease the IFX dose by ≤1.5 mg/kg/infusion q8 wks, up to 6 mg/kg or down to 3 mg/kg, based on clinical response. Primary endpoint was the proportion of patients meeting ACR-Pedi-30, defined as improvement of ≥30% in ≥3 of 6 core variables, & ≤1 of the remaining variables worsened by >30%. Remission was defined as 0 joints with active arthritis, normal ESR, & physician's global assessment ≤10 mm on a 10-cm visual analog scale. 78/122(63.9%) children entered the OLE. The mean(SD) IFX dose at wk 196 was 4.4(1.6)mg/kg. IFX was well-tolerated;14.1% of patients discontinued due to adverse events (AE) from wks 52–204. The distribution/types of AE were similar to those in the first 52 wks & no new safety issues were reported. Among the 36 study patients by wk 204, ACR-Pedi-30/50/70/90 responses were 91.7%(33/36), 83.3%(30/36), 69.4%(25/36), & 50%(18/36), respectively. 39%(14/36) of patients achieved remission. From wk 52 through wk 216, 36.6%(26/71) of patients were positive for IFXantibodies; 57.7%(15/26) of these had an infusion reaction. Continuous IFX+MTX administered up to 4 yrs was safe & effective in JRA patients, although accompanied by a high rate of patient discontinuation, which included subjects in remission.