Pediatric Rheumatology

Oral presentation

2.1 Long-term safety and efficacy of tocilizumab in children with systemic juvenile idiopathic arthritis (JIA)

S Yokota*[1], T Imagawa[1], T Miyamae[1], K Kasai[1], M Mori[1], N Nishimoto[2] and T Kishimoto[2]

Address: [1]Yokohama City University, Yokohama, Kanagawa, Japan and [2]Osaka University, Suita, Osaka, Japan
* Corresponding author

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

Published: 15 September 2008

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

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

Objectives

To evaluate long-term safety and efficacy of tocilizumab in treatment of children with systemic JIA.

Methods

Patients with systemic JIA fulfilled WHO/ILAR criteria were enrolled in long-term extension study immediately after completion of phase II and III trials of tocilizumab. Tocilizumab was intravenously administered at a dose of 8 mg/kg every 2 weeks. Efficacy was assessed every 6 weeks using ACR Pedi 30 Criteria for Improvement.

Results

Sixty seven patients (29 boys and 38 girls) were included in this analysis. Median age was 8 years and median disease duration was 3.8 years. At the time of analysis, 9 patients had discontinued tocilizumab treatment, 4 due to AEs, 4 due to development of anti-tocilizumab antibodies and 1 due to lack of efficacy. Median duration of tocilizumab treatment was 146 weeks. The most frequent AEs were upper respiratory tract infections and gastroenteritis. The incidence rate of serious infections was 10.7 per 100 patient-years. No deaths, malignancies, or autoimmune diseases were observed. ACR Pedi 30, 50 and 70 Improvement Criteria were achieved in 100%, 98% and 93% at Week 96. All patients were treated with oral corticosteroids at the registration and 72% were able to reduce corticosteroid dose by more than 50% at Week 96. Fourteen patients became steroid-free during the study. 4 patients were in remission without tocilizumab itself and any other medications.

Conclusion

The long-term extension study demonstrated sustained clinical improvement and a favourable risk-benefit profile for tocilizumab treatment in children with systemic JIA. Even medication-off status will be expected.