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Open label multicenter study of once weekly Etanercept 0.8 mg/kg in active polyarticular Juvenile idiopathic arthritis (JIA)

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Background

In Europe Etanercept is licensed for the treatment of resistant polyarticular JIA at a dosage of 0.4 mg/kg bw. twice weekly in children older than 4 years.

Objectives

To evaluate the safety and efficacy of Etanercept once weekly 0.8 mg/kg up to 50 mg in a formal trial.

Methods

At each study site an independent ethics committee approved the protocol, and each patient's parent gave written informed consent (EudraCT No. 2007-000255-34). 20 patients 4 to 17 years old were included and received 0.8 mg/kg bw. of etanercept subcutaneously once weekly for 12 weeks "Active" polyarticular disease was defined by the presence of five or more active joints. PedACR30/50/70 criteria were calculated.

Safety assessments were based on adverse events (AE) reported.

Results

15 of 20 JIA patients, 16 girls and 4 boys, mean age 12.9 years, disease duration 4.1 years, already have completed the 12 week study period. The mean dosage was 0.80 +/- 0.04 mg/kg Etanercept. Concomitant treatments were kept stable 3 months before and throughout the study and consisted of NSAID (n = 20), prednisone (n = 4), methotrexate (n = 12), leflunomide (n = 2), sulfsalazine (n = 1). A PedACR 30/50/70 response was reached by 73%/26%/10% of patients after 4 weeks, 86%/73%/40% after 8 weeks and 92%/92%/79% after 12 weeks of treatment. There were 33 AEs but no SAE: 9 minor infections 12 injection site reactions and 12 other AEs. There was no drop out.

Conclusion

These data indicate that once weekly application of Etanercept at double dosage of 0.8 mg/kg bodyweight up to 50 mg per injection is safe and efficacious in polyarticular JIA patients.