

Etanercept's Safety, Efficacy In JIA Persist After 3 Years

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BARCELONA — Etanercept was well tolerated and clinical improvements maintained for up to 3 years in children with polyarticular or systemic juvenile idiopathic arthritis enrolled in an ongoing registry, Edward H. Giannini, Dr.PH., said at the annual European Congress of Rheumatology.

The multicenter, nonrandomized registry included 601 patients between 2 and 18 years assigned to etanercept, methotrexate, or a both based on condition at enrollment. About 75% were female. Mean age was 10 years; 74% were white; 59% had polyarticular onset arthritis. Overall, 198 patients received methotrexate, 105 received etanercept, and 298 were treated with both.

Etanercept was given subcutaneously twice weekly in doses of 0.4 mg/kg, to a maximum of 25 mg, or 0.8 mg/kg once weekly to, at most, 50 mg. Methotrexate was given in doses of at least 10 mg/m² per week, up to 1 mg/kg per week.

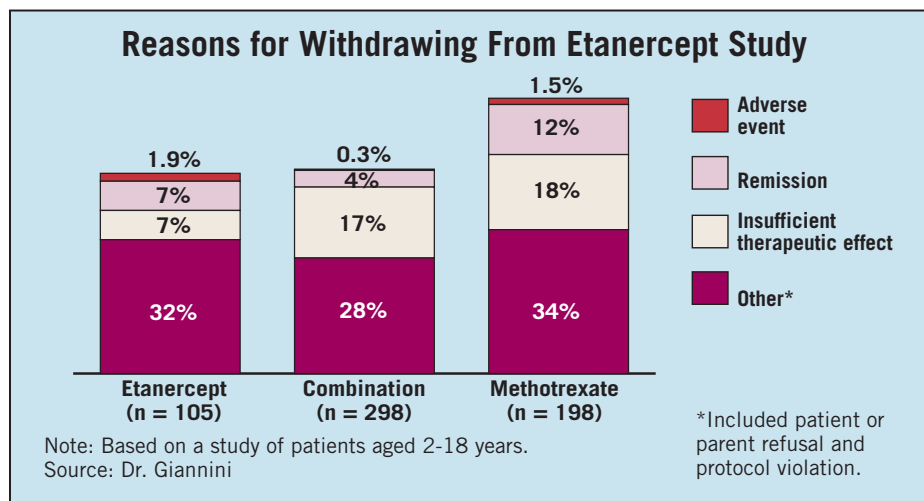
Patients given methotrexate could switch to etanercept or the combination and reenroll, but those taking etanercept who switched to methotrexate could not. To date, the numbers of patients who've completed the study in the methotrexate, etanercept, and combination groups are 55 (28%), 25 (24%), and 79 (27%), respectively, said Dr. Giannini of Cincinnati Children's Hospital Medical Center.

Patients discontinued the study for reasons including remission and inadequate therapeutic effect (see chart). Thirty-four patients initially taking methotrexate were switched to one of the etanercept groups.

Rates of serious adverse events per 100 patient-years were 5.25, 8.36, and 5.78 for patients on methotrexate, etanercept, or the combination, respectively, he wrote in a poster. Serious events included arthritis flare, headache, viral infection, and asthma.

Rates of medically important infections per 100 patient-years were 0.95, 1.97, and 1.98 for the methotrexate, etanercept, and combination groups, respectively. One case of sepsis was reported in a patient on methotrexate and another in a patient on the combination. Five opportunistic infections were reported, two in the methotrexate and three in the combination group. There were no cases of tuberculosis, lymphoma, or other malignancies. New autoimmune features were seen in all groups. One case of lupus was reported.

Active joint counts in the methotrexate, etanercept, and combination groups fell from a mean of 6, 5, and 6 at baseline to 0, 0, and 1 at year 3. Physician global assessment fell from 4, 3, and 4 to 1 for all groups. "However, comparisons between treatment arms are limited by the inherent bias associated with nonrandomized patient assignment and early dropout of nonresponders," Dr. Giannini noted. ■



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¹ Jackson RD et al. Calcium plus Vitamin D supplementation and the Risk of Fractures. *N Eng J Med* V354:7 Feb 16, 2006
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Polyarticular JIA can lead to symmetric arthritis of both large and small joints.

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