

PAEDIATRIC RHEUMATOLOGY

RCT of adalimumab supports anti-TNF therapy for juvenile-onset ankylosing spondylitis

“It is a major task of our community to offer more promotion and support for studies of drugs for children,” says Gerd Horneff, explaining why short-term data from a randomized controlled trial (RCT) in just 32 patients with juvenile-onset ankylosing spondylitis (JoAS) are so welcome. Although adalimumab is approved for adults with axial pathology

despite standard NSAID therapy, “only a few case reports” of therapy for NSAID-refractory JoAS existed before this RCT, with no proven alternative treatment options for these paediatric patients.

“With this short clinical RCT, evidence for efficacy of TNF inhibition in JoAS was given at the highest level for the first time,” states Horneff. Participants, aged 12–17 years and receiving a stable NSAID dose, were randomized during an initial 12-week phase to receive either 40 mg adalimumab ($n = 17$) or placebo ($n = 15$) every other week. Except for those who discontinued therapy through lack of response (one in each group), patients then entered a 12-week open-label phase in which they all received adalimumab. Inclusion criteria were based on MRI and clinical evidence of active disease.

Patients receiving adalimumab, which was well tolerated, showed improvements that intensified with ongoing treatment. The primary outcome measure was

Spondyloarthritis International Society criteria for 40% improvement from baseline (ASAS40), with secondary measures comprising scores of pain, inflammation and function. ASAS40 rates at weeks 4, 8 and 12 were 41%, 53% and 53%, respectively, in the adalimumab group, compared with 20%, 33% and 33% for placebo; superiority of adalimumab by this measure was only statistically significant at week 8, but significant improvements in other measures were noted also at week 12.

“TNF antagonists open new avenues for treatment of juvenile SpA and especially JoAS,” says Horneff. He adds that an RCT of etanercept for juvenile SpA is underway.

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Original article Horneff, G. *et al.* Double blind, placebo-controlled randomized trial with adalimumab for treatment of juvenile onset ankylosing spondylitis (JoAS): significant short term improvement. *Arthritis Res. Ther.* 14, R230 (2012)

