Abstract

Purpose:

To determine longer-term outcomes of participants enrolled from a single center in the SYCAMORE trial, a randomized placebo-controlled trial of adalimumab versus placebo in children with juvenile idiopathic arthritis-associated uveitis (JIA-U) uncontrolled on methotrexate.

Design:

Retrospective interventional case series.

Methods:

Medical records of all 28 SYCAMORE participants recruited at the Bristol Eye Hospital were reviewed at approximately 3-monthly intervals up to 5 years from the trial randomization date. Uveitis activity, treatment course, visual outcomes, ocular complications and adverse events were recorded. Data are presented using summary statistics.

Results:

Following withdrawal of the investigational medicinal product (IMP), 25 of the 28 participants were started on adalimumab for active juvenile idiopathic arthritis-associated uveitis (JIA-U). Of the 12 participants in the active treatment arm of the SYCAMORE study, 11 (92%) were restarted on adalimumab after withdrawal of the IMP for active JIA-U (median time to flare 188 days (range 42-413)). Two participants stopped adalimumab for uncontrolled JIA-U. One participant had a

reduction in vision to 0.3 due to cataract. Mean visual acuity for the remaining 27 participants was -0.04 (right eye) and -0.05 (left eye).

Conclusions: Drug-induced remission of JIA-U did not persist when adalimumab was withdrawn after 1-2 years treatment. Adalimumab was well tolerated and visual acuity outcomes were excellent.

Highlights

1. Follow-up data on large randomised-controlled trial on JIA-U
2. Drug-induced remission of JIA-U did not persist when adalimumab was withdrawn after 1-2 years
3. This study supports a longer-term role for adalimumab in the treatment of refractory JIA-U