Reviewer's report

Title: Randomised controlled trial of the clinical effectiveness, safety and cost effectiveness of adalimumab in combination with methotrexate for the treatment of juvenile idiopathic arthritis associated uveitis (SYCAMORE)

Version: 2
Date: 23 October 2013

Reviewer: Kelli Allen

Reviewer's report:

Minor essential revisions:
1. There are many abbreviations in this paper and most are spelled out before the first use, but a few are not. Please check manuscript for these instances (e.g., s/c in both abstract and manuscript, HUI2, SSI, R&D, GCP, CTU, EULAR, ILAR
2. Rationale paragraph 4, 1st sentence: it may help to state the kind of study or case series this was.
3. Under the "Potential Risks and Benefits" section, it seems like the next 2 labels ("Potential Risks" and "Known Potential Benefits") are sub-sections; consider labeling in a different way to aid the reader.
4. Last sentence of Potential Risks reads more like instructions to physicians than more information about risks. Recommend removing.
5. Known Potential Benefits section - 1st sentence, state what these were studies of (what drug(s)). Also, is the information in the second paragraph on the same studies noted in the 2nd paragraph? These 2 paragraphs could be better integrated.
6. Last sentence of sample size section may be better placed earlier.
7. Combine last 3 paragraphs of Randomisation as these are all very related and brief paragraphs.
8. Analysis section: Recommend omitting 1st sentence. Typically a full analysis plan (at least for main hypotheses) should be completed before a trial starts, so this sentence is a bit concerning. It would be better just to state the analysis plans that have been established at this point.
9. Analysis plan 3rd paragraph, recommend omitting 2nd and 3rd sentences since these are really not about analyses per se.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests.