Reviewer's report

Title: An open-label randomized clinical trial of prophylactic paracetamol co-administered with 7-valent pneumococcal conjugate vaccine and hexavalent diphtheria toxoid, tetanus toxoid, 3-component acellular pertussis, hepatitis B, inactivated polio virus, and Haemophilus influenzae type b vaccine

Version: 2 Date: 17 January 2013

Reviewer: Robert Chen

Reviewer's report:

This paper reports the findings of an open label study of efficacy and safety of ~300 healthy infants randomized to routine pediatric vaccination in Germany with or without prophylactic use of paracetamol. The study itself was started in March 2005 and the current paper represents a shortened version of a previous submission, addressing the prior reviewer comments.

The current paper satisfactorily addresses the comments of prior reviewers.

Minor essential revision:

Since fever is a key outcome in this study, the Methods should explicitly state to what extent this study was or was not able to follow the Brighton Collaboration case definition for fever (PMID:14741143).

Level of interest: An article whose findings are important to those with closely related research interests

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'