Reviewer's report

Title: Randomized clinical trials with inadequate blinding report enhanced placebo effects for intervention groups and nocebo effects for placebo groups: a protocol for a meta-epidemiological study of PDE-5 inhibitors

Version: 1 Date: 10 September 2012

Reviewer: Ulrich Grouven

Reviewer's report:

Overall, the manuscript is clearly written and hypothesis, rationale, and methodology of the planned study are sound and adequately described.

Nonetheless, I have some remarks and minor points which need clarification.

Minor Essential Revisions

1. Title and abstract screening is described to be performed by only 1 reviewer. Screening by two independent reviewers is recommended (PRISMA statement, item 9) and would reduce potential errors.
2. It is not clear how the authors plan to deal with RCTs in which only final score values (not change from baseline) are reported.
3. The statement “Between meta-analysis heterogeneity variance will be calculated to express the variability in bias with P value.” (page 12) needs further elaboration (what exactly is meant? Test of interaction?)
4. It is not clear why effect differences in the case of two subgroups are assessed by the overlap of CIs instead of a significance test (as planned for more than 2 subgroups).
5. The use of logistic regression for performing sensitivity analyses needs to be explained in more detail.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.