Reviewer's report

Title: A multi-centre randomised controlled study of pre-IVF outpatient hysteroscopy in women with recurrent IVF implantation failure: Trial of Outpatient Hysteroscopy - [TROPHY] in IVF

Version: 1  Date: 3 August 2009

Reviewer: Sjors Coppus

Reviewer's report:

Major Compulsory Revisions
- none

Minor Essential Revisions
- Regarding the protocol, a few issues have to be clarified before publication in my opinion:
  - In the protocol a statement about the expected incidence of intra-uterine pathology is missing. This is stated in the patient information though, where the authors mention that they expect to find polyps/fibroids or other pathology in 25% of women undergoing office hysteroscopy.
  - this is an important point, as the difference in outcome between both groups can only be attributed to those 25% cases with cavitary pathology that is treated during OH. The other 75% of randomised women will not contribute to a difference between both arms.
  - As a result, the number of women that have to be randomized to detect the minimally important difference of 10% increase in live birth in the OH group is quite large, with a total number of 758, as a result of which I question the feasibility of this study. Do the authors have an assumption about the number of women that are eligible for inclusion annually in the participating centers?
  - Regarding the design of the trial, did the authors consider a design in which all women with recurrent IVF implantation failure undergo a saline infusion contrast sonography, and to randomize between OH or non-OH in only those women with an abnormality on SIS? This would most likely reduce the sample size considerably.

Discretionary Revisions
- None

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