Reviewer's report

Title: Fibrinogen concentrate versus placebo for treatment of postpartum haemorrhage: study protocol for a randomised controlled trial

Version: 2 Date: 23 December 2014

Reviewer: Simon Stanworth

Reviewer's report:

This is a well written paper describing the rationale and detail for a randomized trial of targetted concentrated fibrinogen infusion, using concentrate.

Could the background be shortened and focussed on the condition (PPH), the intervention, and the need for research. It is important to cross-reference to any relevant systematic reviews of the intervention. Are any other trials of fibrinogen in PPH completed and any differences in design? The authors indicate delays eg turnaround times for testing and blood components, but other groups have published on alternative strategies to minimise eg to reduce laboratory times for testing, or pre-thawed plasma. Compared to other data, the reported confidence intervals for many of the results presented in the background actually seem quite narrow eg measures of bleeding, transfusion, testing.

The main trial objective is well described. Could the authors provide justification for use of blood products as main outcome – data from cardiac surgery and trauma suggest general limitations to the use of reduction in transfusion needs as main endpoints.

The sample size calculation is not easy to follow, but reflects the issues of means and different scales. Should the primary outcome just look at red cell requirments (see next point)? Please add some justification for the clinical meaningfullness for the expected differences in use of blood. How will the authors deal with protocol violations/deviations?

Crucial to interpretation of blood use will be operational aspects and blinding. What resources are required to deliver on this trial – and how does this operate out of routine hours? How much will this affect ‘routine’ practice and standard procedures, and crucially the decision to give FFP? Has any consideration been given to testing the success of blinding?

The discussion should also mention perceived limitations of the study. Have any (or no) subgroup analyses been pre-specified?

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

Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I have no competing interests