Author's response to reviews

Title: Immediate vs. Delayed Insertion of Intrauterine Contraception after Second Trimester Abortion: Protocol and Rationale for a Randomized Controlled Trial

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Version: 3 Date: 14 March 2011

Author's response to reviews: see over
Editors-in-Chief,
BMC Trials,

2011 March 14th,

Dear Sirs;

Thank you for reviewing this randomized controlled trial protocol manuscript “Immediate vs. Delayed Insertion of Intrauterine Contraception after Second Trimester Abortion: Protocol and Rationale for a Randomized Controlled Trial ”, as submitted for consideration of publication in Biomed Central’s journal “Trials”.

We have incorporated requested changes from the peer reviewer as forwarded and have these specific responses:

• In the abstract could some rationale for the study be provided in the background?
  
  ▪ We have added the following to the background section of the abstract:

  “Decision analysis suggests the novel strategy could substantially reduce subsequent unintended pregnancies and abortions.”

• In the introduction - second para: what evidence is there that second trimester women who have IUD at 4 weeks have higher rates of expulsion?

  ▪ In fact, although product monographs exclude our proposed study population from the benefit of immediate insertion of contraception at the time of abortion, we have not found evidence that this practice is beneficial, and we believe there is strong theoretical and observation study support to show withholding the contraception at this opportune time fails to prevent a significant number of subsequent unintended pregnancies.

  ▪ We have added the following to the second paragraph of the Introduction:

  “This recommendation appears to be founded upon a theoretical risk of greater rates for expulsion prior to uterine involution, as we were unable to find published evidence to support this assertion.”

• I liked the data linkage approach to attrition although there is a problem if expulsions have not been detected. Any thought to scheduling a 12 month visit (instead of making it an offer)
Thank you for this suggestion. In fact we have in practice been asking every participant to return for a twelve month visit, and have revised the section “outcome determination” on page 10 of the protocol to reflect this:

- The word “may” (return for follow up exam) has been replaced with “are asked to”.

We thank you for these thoughtful reflections and for any other suggestions you may have.

With kind regards,

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