Author's response to reviews

Title: International Active Surveillance Study of Women Taking Oral Contraceptives (INAS-OC Study)

Authors:

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Version: 3 Date: 10 March 2009

Author's response to reviews: see over
Dear Ms. Hoffman,

MS: 1220621916238169
International Active Surveillance Study of Women Taking Oral Contraceptives (INAS-OC Study)
Juergen C Dinger, Kristina Voigt and Anita Assmann

Thank you for considering our manuscript for publication in BMC Medical Research Methodology. We also thank the reviewer for his/her comments.

The investigators and the members of the Safety Monitoring and Advisory Council do not agree that the submitted document is a marketing document. Actually, the study protocol was approved by the FDA, by Institutional Review Boards as well as by epidemiologists and gynecologists of international reputation, who have been involved in numerous Cochran reviews. It is hardly conceivable that a “marketing” document can get over these hurdles.

However, the manuscript has been amended in accordance with the factual comments received, and we hope you will now find it acceptable for publication.

Please find attached our revised manuscript along with a detailed response to the reviewer’s comments below.

Comment 1: “This specific article is written … uncritically of the possible weaknesses of the design.”

Author response: The study is not conducted as a randomized double-blind clinical trial. It is a non-interventional study with the strengths and weaknesses of all other well conducted non-interventional cohort studies. The potential weaknesses of this study type are now addressed in the new ‘Discussion’ section.
Comment 2: “[manuscript] is not structured according to e.g. STROBE guidelines.”

Author response: The study protocol was written and approved before the publication of the STROBE guidelines. We are not in the position to change the whole structure of the study protocol which was approved by FDA. Such a change would need a very lengthy re-discussion with the competent authorities.

The structure of the manuscript follows the structure given at the BMC Medical Research Methodology website. In addition, the study protocol follows in most aspects the GCP guidelines. Furthermore, based on the reviewers’ comments on reimbursement and publication, we have included additional information which deal with the issues raised by the reviewer. We would also like to point out, that we found a number of study protocols published in BMC journals which have a similar structure to our study protocol.

Comment 3: “Only four references are given, …”

Author response: The number of references has been increased to seventeen.

Comment 4: “… the paper could be much more specific of the methods and feasibility.”

Author response: The methods section has been amended and the feasibility of crucial methods is now discussed.

Comment 5: “Compensation to physician is not told”

Author response: According to our experience a participating physician will need approx. one hour and has to discuss the study with approx. four patients to identify two patients who are actually signing the informed consent form. The running costs of a doctor’s practise (salaries of staff, maintenance of equipment, cleaning, rent, etc.) are very different from country to country and from continent to continent (in this study Europe and the United States). We reimburse the participating physicians based on the country-specific running costs. Thus there is no payment for the doctor’s work but only for the running costs of the practice. The payment process is transparent, completely documented, and will only be based on work actually performed. We have added this information to the manuscript (section Ethics and Privacy).

Comment 6: “Conditions of contract (what the researchers can publish) are not told, neither the content of the agreement with the Advisory Council”

Author response: The investigators will publish the study results. The manuscripts will be approved by the Safety Monitoring and Advisory Council (SMAC) before submission. Bayer Schering Pharma has no right to prevent
the publication of results or to influence the interpretation of data. This information has been added to the Ethics and Privacy section. Furthermore, the relevant terms of reference for SMAC were integrated in section Safety Monitoring and Advisory Council

Comment 7: “Please ensure … a more balanced description of the different arms of the Study Protocol.”

Author response: This request has been implemented by changing the Background section.

Please do not hesitate to contact me if you have any further queries.

I look forward to hearing from you.

Yours sincerely,

Jürgen C. Dinger, MD, PhD