Author's response to reviews

Title: Induction of labour with a Foley catheter or oral misoprostol at term, the PROBAAT-II study, a multicentre randomised controlled trial

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Author's response to reviews: see over
Dear Sir/Madam,

Please find enclosed a manuscript entitled: Induction of labour with a Foley catheter or oral misoprostol at term – a multicentre randomised controlled trial (PROBAAT-II trial protocol) by Mieke LG ten Eikelder, Femke Neervoort, Katrien Oude Rengerink, Marta Jozwiak, Jan-Willem de Leeuw, Irene de Graaf, Maria G van Pampus, Maureen Franssen, Martijn Oudijk, Paulien van der Salm, Mallory Woiski, Paula JM Pernet, A Hanneke Feitsma, Huib van Vliet, Martina Porath, Frans Roumen, Erik van Beek, Hans Versendaal, Marion Heres, Ben Willem J Mol, Kitty WM Bloemenkamp, which I am submitting for exclusive consideration of publication as a research protocol in BMC Pregnancy and Childbirth.

Induction of labour is a frequent obstetric intervention, comprising 20-30% of births. A substantial proportion of women in whom labour is induced have an unfavourable cervix. A variety of methods is available to ripen the cervix, including mechanical (e.g. Foley catheter) and pharmacological (e.g. misoprostol). Conflicting evidence exists on safety and (cost-)effectiveness of these methods. Therefore, the aim of this study will be to evaluate safety and (cost-)effectiveness of induction of labour with a transcervical Foley catheter, compared to oral misoprostol in 1860 term pregnant women with an unfavourable cervix. The study will be performed within the Dutch Consortium for Studies in Women’s Health and Reproductivity. Randomisation started 18 July 2012.

We hope that this manuscript will be considered for publication in the BMC Pregnancy and Childbirth. The outcome of this study could contribute to a safer and effective way of inducing labour worldwide.

All authors listed have contributed sufficiently to the project to be included as authors, and all those who are qualified to be authors are listed in the author byline. To the best of our knowledge, no conflict of interest, financial or other, exists. We have included acknowledgements, conflicts of interest, and funding sources after the discussion.

As proof of ethics and funding I send a copy of the original letters. The study protocol is approved by the Ethics committee of the Academic Medical Centre Amsterdam (MEC NL 35278.018.11), and the institutional review boards of participating hospitals. Funding is provided by Fonds Nuts Ohra, a Dutch organisation for Health Research and Development.

The content of the manuscript is original and it has not been published or accepted for publication, either in whole or in part. No part of the manuscript is currently under consideration for publication elsewhere. The trial is registered with the Netherlands Trial Register (NTR 3466).

Yours Sincerely,

Mieke ten Eikelder, MD