



Department of Women's and  
Children's Health,  
Division of Obstetrics and  
Gynecology,

**MINUTES FOR AUTHOR'S MEETING  
NORDIC ABORTION COLLABORATIVE STUDY 2011-2014**

**THURSDAY 12<sup>th</sup> June 2014  
RADISSON WATERFRONT STOCKHOLM, SWEDEN**

**Participants:**

Dr. Kevin Sunde Oppegaard, MD, PhD, Hammerfest, Norway

Prof. Kristina Gemzell Danielsson, MD, PhD, WHO centre, Dept. of Women's and  
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Prof. Oskari Heikinheimo, MD, PhD, Helsinki, Finland

The Lancet has now accepted the study for publication, pending receipt of the Research-In-Context Panel. The authors draft a panel, consisting of search strategies for the literature review, as well as an Interpretation. Kevin forwards the RiC Panel to the Editor.

Following the successful conclusion for the first collaborative study funded by NFOG, we discuss the possibility of a new study together. It would be desirable to have both Denmark and Iceland join us, in order to make this a truly Nordic collaboration. Charlotte Wilken-Jensen (DK) and Jens A. Guðmundsson (IS) agree to join our group.

A key to making our last trial work was the very good personal and professional friendly relationships we enjoyed with each other and being able to communicate rapidly by email, whenever communication was needed (particularly when drafting the manuscript and afterwards, during the review process for The Lancet). We know from experience that we did a lot of revision during the weekends! It also helped that we only had one centre from each country.

Regarding funding for a future trial: a big obstacle from the last project was lack of NFOG funding for statistician costs, the cost for making a web-based CRF, the lack of funding for material costs – as well as no funding for our collaborator Christian, from Vienna. There is currently DKR 200 000 allocated for such costs in NFOG's additional fund and we can apply for that money to finance statistician costs, drug manufacturing costs and the cost of making a web-designed case-report form for a

future project. The NFOG fund for meeting expenses application deadline is October 1st. We should have applications for both funds in by this date. Kristina mentioned that she previously has prepared a protocol for a trial; if it is updated, we could modify it for our purposes and attach it to any funding applications.

We propose the following new study: a randomised controlled trial comparing two different dosage regimens of vaginal (?) misoprostol for treating missed abortion (i.e. a non-viable pregnancy with no bleeding), it would be important to include anembryonic pregnancies as well ('blighted ovum' in our terminology). Probably two arms, possibly a third surgical arm? Treatment with mifepristone should be discussed but this would decrease generalizability, as mifepristone availability is restricted. Ideally, the trial should have a placebo-controlled design, where the hospital pharmacy makes capsules of ground-up misoprostol, so that all women receive treatment with misoprostol but no one knows which dosage they are receiving. Main outcomes could be number of women requiring surgery and time to complete treatment. We will need involvement with a statistician at an early stage of the planning. The statistician on our previous trial from Karolinska was excellent but she is currently on maternity leave. We suggest that Kristina contacts the same department at Karolinska for a new statistician, while we are drafting the protocol. The statistician's calculations of patient numbers will be quite crucial for the whole trial: time frame, number of centres needed etc. We will have at least five centres participating, one from each country. Kevin has already been contacted by a group of private practicing gynaecologists in Oslo, who say they perform a lot of ultrasounds in early pregnancy and have a substantial amount of women with missed abortions. Apparently, the university hospital in Oslo refuses to admit the women (on the grounds of resource problems?) and insists that the private specialists treat these women with misoprostol themselves. This private clinic could be an ideal collaborative partner from Norway and could be combined with the department in Lillehammer. If the statistician calculates that we need a lot of cases, we could consider bringing other clinics on board but they must be very well organised!

We have approximately DKR 10 000 left from our last project, which is probably not enough to cover all the costs of a meeting (a meeting room/lunch costs 7000-8000 kroner). Nonetheless, we could still plan for a meeting with the main authors from each country after the summer - possibly in Stockholm when Jens is visiting. We could plan for a couple of meetings a year and the rest of the communication by email, as we did last time. If we start drafting a protocol shortly, apply for funds and ethical committee permission after the summer, design the web-based CRF, and manufacture the drugs etc. next spring. We could be ready to start recruiting after the summer holidays 2015. Then it might take two years to recruit, depending on how the frequency of missed abortions is.

We know from experience that such a trial might take a few years, so we need

dedicated people who have staying power and do not give up because the recruiting rate is going slowly! We would welcome participation of a rising star in the department, if the seniors feel this would be conducive. I envisage such a trial taking two-three years (our last trial took four years). Presentation at NFOG 2018 or 2021?

Stockholm, June 12th, 2014  
Kevin Sunde Oppegaard