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

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

FRIDAY-SATURDAY 28th February- 1st March 2013
RADISSON POLAR HOTEL SPITSBERGEN NORWAY

Participants:
Dr. Kevin Sunde Oppegaard, Md, PhD, Hammerfest, Norway,
Prof. Kristina Gemzell Danielsson, WHO centre, Dept of Women´s and Children´s Health, Div for Obst & Gyn, Karolinska Institutet, Stockholm, Sweden.
Dr. Christian Fiala, MD, PhD, GynMed Ambulatorium, Vlenna, Austria,
Prof. Oskari Heikinheimo, MD, PhD, Helsinki, Finland

A. The trial has now been concluded, the data analysed and draft manuscript written. Submission version of manuscript prepared together with cover letter to be submitted to The Lancet for peer review. All authors have signed author's form.

B. Experiences and lessons from our multicenter, multinational trial

In our view, this has been a rich experience and a considerable achievement. We have managed to plan and conduct an international multicenter trial without any support from the pharmaceutical industry, or other major sponsors. Financial support from NFOG has been important for our meetings and we hope to be able to present our trial at the NFOG congress as an example of what the NFOG fund has reaped. We have now established a working group that will be able to conduct multicenter, international randomized trials in the future. Our trial was not without technical difficulties and lessons to be learned. Establishing an internet-based case report form was a major technical achievement and was used by study nurses for data punching in all countries without difficulty. The CRF was comprehensive enough but an omission was forgetting to register the patient groups on the form. The primary endpoint was also not a dichotomous value, resulting in time-consuming data-checking and analysis. The three ongoing pregnancies were unexpected – maybe a check-list, used at Karolinska, could have prevented these? Losing our statistician just before data analysis was a setback but the new statistician was extremely on the ball and helpful. The statistical analysis was very

expensive however, and it will be necessary for future trials to secure funding for this. The trial also resulted in the improvement of the medical abortion regimen at Ullevål, where many patients were taking misoprostol before a 24-hour interval after mifepristone. Nonetheless, there was no difference in complications between the centers. We discussed whether a pilot study would have uncovered the weaknesses of the study design but conclude that this would have proved time-consuming and labour-intensive for little gain. A problem that the centers had such different recruiting rates which resulted in a prolonged study period.

C. Publication strategy for first paper: Lancet, WHO bulletin, Human Reproduction

D. Prepare statements for publication.
   We await the results of the peer-review.

E. Planning and implementation of second study: Contraceptive use following medical abortion.

The database is currently locked pending submission of the manuscript. We will survey how many patients recruited agreed to be contacted for one-year follow-up. A problem now that more than two years has passed since their initial contact.

F. Third study: Medical termination of pregnancy of unknown location. Discussion of feasibility. Because of the failure of the DUO-test, there is no alternative we can use. We can not carry out this project at the moment.

G. Brain-storming for further studies/projects.

Treatment of miscarriage, based on serum hCG – progesterone levels.
Ongoing pregnancies after medical abortion. Repeated doses of medical abortion versus surgery. Immediate insertion of iud after medical abortion. Pain treatment during abortion.

H. Further meeting

Pending outcome of manuscript submission. Propose meeting at NFOG congress in June.

I. AOB

Longyearbyen, March 1st, 2014
Kevin Sunde Oppegaard