Intitutionen för Kvinnors och Barns Hälsa
Enheten för Obstetrik och Gynekologi

Nordic Abortion Collaborative study: Investigator meeting

16.06.2012, 2 pm to 6 pm at the Radisson Blu Hotel Norge, Bergen, Norway

Update and report on on-going Trial

Approx. 600 women recruited so far. Large differences in data entry and drop-out rates between centres. Data for only 228 entered so far – Norway and Sweden lack information for many patients.

Interim analysis

150 women. No difference in efficacy (complete abortions) and safety.
Significantly more women were lost to FU in the control group (29%) vs. the intervention group (N=1) ($p<0.001$).
92% found the home test easy to use.
92% in the intervention group preferred self-assessment vs. 54% in the control group in the case of a future abortion.

Current recruitment status from each center. Difficulties and delays for mutual discussion.

Finland: 44 patients recruited, all data entered. Study has been progressing disappointingly slowly, mainly due to conflict with another study. However, very few drop-outs.

Sweden: 200 recruited, data entered for 75. Recruitment has also been slower than expected due to conflict with other studies. 29% drop out in control group, 1% in intervention group. Very difficult to contact drop-outs, despite detailed information to patients at recruitment.

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Austria: 103 patients, all data entered consecutively. Lost to follow-up 14%. Only 40% of patients seem to be eligible for inclusion, reasons given for not being eligible: not eligible for treatment, wish to have follow-up regardless, too early pregnancy to be included, many women wish to attend their private gynaecologist, don't speak English. Lost to follow-up 14%. All data entered.

Norway: About 260 recruited, data for 6 entered. No progress since last meeting. Reason for halting recruitment being worries that the time difference to completion between the other centres would be too large. Large number of drop-outs, difficult to contact patients for follow-up.

Study challenges and plans for each center.

Sweden and Norway should have no problem recruiting the calculated 300 women within a relatively short time frame. Norway plans for data entry in the immediate future. Austria would possibly need another year, Finland likewise. Two alternatives discussed: 1) wait until each center has 300 with no definite cut off date 2) each center recruits to the best of their ability with the final inclusion for the study by December 2012. Hopefully this would ensure enough patients to make the study eligible for publication. All authors agree that option 2) would be the preferred one.

Other similar trial submitted to Contraception, observational trial Edinburgh (Cameron ST: Telephone FU and self-performed urine pregnancy testing after early medical abortion: a service evaluation). Winikoff et al. recruiting in third world countries, their trial still labelled as "recruiting" on ClinicalTrials.org.

Our trial is randomised and multi centre and will be larger than the already published study. Although no longer unique, it has potential for being more robust.

The protocol for ClinicalTrials.gov was entered December 2011, while the first patients were recruited August 2011. This could be a potential obstacle to publication in certain journals.

Loss to follow up

The main outcome is follow-up. A major concern is that approx. a third of recruited women are lost to follow-up in Norway and Sweden. Pre-recruitment counselling is essential to ensure that the women who elect to participate in the trial realise that follow-up is a major outcome of the trial and can be contacted. Maybe call more than twice – if possible. Maybe schedule follow-up calls in the evening if patient cannot be reached during daytime?

Case-Report forms: Data collection and database
Database is functioning well, no problems with entering data or access for analysis.

Financial status - grants, applications etc
NFOG: approx. Dkr 30000 left, Dkr 14000 must be used before the end of 2012. Request permission to fund a meeting room and dinner at FIGO, possibly travel expenses for Kristina if presenting interim analysis. Study eligible for one further grant from NFOG. Will apply for more NFOG funding in September, deadline October 1st. It is therefore important to have as much data entered during the summer before September for interim analyses and application for funding from NFOG.

ESC grant used for tests and study nurses, plus funding travel for Christian, who is not eligible for NFOG cover. No further application possible.

Presentations/ conferences

Kristina requested to present interim data at NFOG, all authors unanimous in agreement that this is desirable. Would also be advantageous to present interim data at FIGO in Rome in October.

Future meetings

As all authors expect to attend FIGO conference in Rome in October, this would be suitable for a meeting. Date and venue to be set as early as possible. The conference in Rome will be at a venue near the airport. Interim analyses to be presented.

After recruitment is halted in December it would be desirable for meeting in early March 2013 to discuss results and begin drafting outline for the first paper. Proposal to meet in northern Norway for weekend 7th-10th March.