

Minutes of the meeting on December 19th, 2014, WHO Centre, Karolinska Hospital

Present: Kevin Sunde Oppegaard, Oskari Heikinheimo, Christian Fiala, Johan Bring, Kristina Gemzell-Danielsson

A. Update on the protocol

Minor adjustments and clarifications are made to the statistical methods and endpoints. The protocol is now finalised and ready for funding applications and applications to the regulatory bodies.

B. Update on funding situation

The funding situation was discussed. NFOG has provided funding for 3 study meetings. The application for the extra DKK 200 000 that NFOG had allocated during the general assembly in Bergen June 2012 has been sent but no information from the scientific committee has been forthcoming. Oskari will query this during the next NFOG board meeting in January. An application to the research council at Lillehammer will be submitted and all participating centres should submit their own grant applications to cover local costs. The big grant application to NordForsk will be decided during March 2015. Funding from NordForsk will be critical to the study. The preliminary estimate for manufacturing mifepristone placebo and drug tablets for 600 patients from APL is SEK 990 000, while the Karolinska Trial Alliance has quoted a price of 2000 SEK/randomised patient: SEK 1 280 000 in total for 640 patients. An alternative drug supplier, Sun Pharma, has been considered. However they are unable to give us a quote as they have recently merged with Ranbaxy and are busy with reorganization. Randomising patients could be done locally at the WHO Centre and electronically by Internet. However, the challenges of conducting such a large study with up to 10 centres will probably be considerable. Without a major funding source, it will not be possible to carry out a multicentre, multinational drug trial of this scope.

C. Finalising the CRF

Minor adjustments to the CRF are made and it is considered ready for applications.

D. Logistics and applications.

Further work on the trial will be made pending successful grant applications.

E. Next meeting

We estimate a meeting before the summer, should our grant applications be successful.

F. AOB

Charlotte will unfortunately no longer be able to participate in our study. A replacement Danish project leader will be sought after our funding situation is clarified during the spring of 2015.