

Interim report for granted project

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Date of sending out the form:	20-10-2016
Contact person/applicant:	H. Kopp Kallner
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Title of the granted project	Randomized double blind study of mepivacaine or placebo for pain relief at insertion of intrauterine contraception.
Amount granted by the ESC (in euro)	4626
Initial funding (part of the grant received already) in euro:	3470
Final amount to be paid by ESC (in euro):	1156
Project number:	P-2015-B-06
Allocated mentor:	G. Bartfai
Date project actually started:	17-12-2014
Planned date of completion:	31-08-2017
Have there been any problems or issues with starting or continuing this project? If so, what impact will that have on your planned completion date?	Yes, one of the midwives in the project has changed where she works and she is now - after a break of 6 months- continuing the study in her new workplace
Have you discussed the project status and any problems with your Mentor?	No

Please provide a synopsis of your findings and data so far (max 500 words)

We performed an interim analysis of 21 women in the intervention group and 20 women in the placebo group. 16 women in the active group received placebo and 5 women Jaydess. In the placebo group 15 women received Mirena and 2 Jaydess. 19 women in the active group would choose to have another insertion of an IUC and 18 women in the placebo group. At three months 20 women in the active group has continued use of the IUC compared to 17 in the placebo group. None of these differences reached statistical significance.

In an interim analysis (the study is double blind) we could see an effect of the treatment with a mean VAS score of pain at IUC insertion of 5.462 in the active group compared to 6.360 in the placebo group. However, as the effect was in the estimated size we need to complete the study in accordance with the power calculation. The study has the potential to show a difference in effect size with the planned sample size.

We have included more than 4/5 of the women needed.

I would very much appreciate if these results are kept confidential as I am now planning a larger study.

Please provide a current budget on how much you have spent to date. Receipts may be requested.

We have spent about half of the money requested. The study is by no means fully funded by the ESC grant but extremely appreciated! Since the interim analysis we have recruited additional individuals and are expecting to complete the study recruitment by March.

At 30 min per individual recruited we estimate
41x15 Euro=615 Euro for nurse midwife
41x15 Euro=615 Euro for study coordinator

for the included individuals in the study at the interim analysis

Add any other information you feel we should have at this stage.

I would very much appreciate if these results are kept confidential as I am now planning a larger multicenter study.

Full Name

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