Final report for granted project

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Title of the granted project	Non-invasive intrauterine instillation of Mepivacain for pain relief at insertion of intrauterine devices: A double-blind randomized controlled trial.
Amount granted by the ESC (in euro)	4626
Project number:	ESC P-2015-B-06
Allocated mentor:	G. Bartfai
Date project actually started:	01-11-2015
Date of completion:	31-05-2017
Please provide a report of your findings and data.	Authors: Niklas Envall1,2, Helena Graflund Lagercrantz3, Jessica Sunesson4 and Helena Kopp Kallner1,3 This trial was designed as a single center, double-blinded randomized controlled trial to evaluate efficacy of intrauterine instillation of Mepivacain for pain relief before insertion of an IUD compared to placebo. Allocation ratio was 1:1. The study was performed at the Youth Clinic in Upplands Väsby (center 1) starting in November 2013 and ending in May 2017. Due to slow recruitment and staff issues The RFSU Clinic was added as a second study center (center 2). The allocation ratio of intervention to placebo was 1:1 with random block size of 6-10 Primary outcome measure was pain on a VAS at insertion of the IUD. Secondary outcomes included pain at instillation of the drug, tenaculum placement, sounding and before leaving the clinic. Acceptability of the intervention was measured as willingness to use the method again and recommending the method to a friend. Acceptability of the insertion procedure was measured as stating if the procedure overall was easier, as or worse than expected. Continued use of IUD, reasons for discontinuation and acceptability of IUD as willingness to use again and recommending IUD use to a friend was measured at follow up at 3 and 6 months. Out of 105 patients assessed for eligibility, 86 (82%) accepted participation and provided informed consent. Finally, 81 participants were included in the analysis. Mean VAS-score was 4,63 in the treatment group (n=41, SD=2,21) compared to 5,67 in the placebo group (n=40, SD=2,62, p=0.058). In the intervention group receiving the study drug, 3/41 patients (7.3%) experienced the procedure as worse than expected compared to 14/40 (35%) in the placebo group.

Please provide a final detailed budget on how much you have spent. Was any money not spent? Receipts may be requested.	86 x 15 Euro = 1290 Euro for nurse midwife 86 x 15 Euro = 1290 Euro for study coordinator Cost for principal investigator 20 hours total = 1000 Euro Cost for consumables, publication and write up = 1046 Euro We are still waiting for the publication costs but will submit before Christmas.
How will your findings be presented?	Publication in journal
Was your paper published? Indicate journal and acceptance date	Submission planned before Christmas
Please let us know whether having a mentor has been helpful or not	I did not have a mentor that I know of
Full Name	Helena Kopp Kallner
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