

Final report form

Date of sending out the form:

Thursday, May 5, 2022

Contact person/applicant:

K. Brandell

Country

Sweden

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Title of the granted project

Efficacy of Very Early Medical Abortion – a randomized controlled non-inferiority trial

Amount granted by the ESC (in euro)

9500

Project number:

P-2019-A-03

Allocated mentor:

S. Cameron

Date project actually started:

Friday, February 1, 2019

Date of completion:

Tuesday, May 3, 2022

Please provide a report of your findings and data.

Study still ongoing, delays due to Covid-pandemic and slow recruitment at some sites.

We have increased number of sites to compensate for this and now this study is ongoing at 20 sites in 7 countries (Sweden 9, Scotland 2, Finland 1, Denmark 1, Norway 1, Nepal 4, New Zealand 1 and Australia 1).

We halve recruited 801 study participants (53%) as of today (03052022) of planned total of 1500.

2 evaluations from our Data Safety Monitoring Board have been performed (sep 2020, sept 2021), they found a total 10 SAE/AE and 4 ectopic pregnancies(EP) (all EP in intervention-group) but only one ruptured and their conclusion was that there is no reason not to continue with the study as planned but to try to increase recruitment pace.

Please provide a final detailed budget on how much you have spent. Was any money not spent? Receipts may be requested.

Overhead	1331
EUR	
Travel-expenses	54 EUR
Statistics software (STATA)	417
EUR	
New Zealand recruitment (200\$/patient)	
2079 EUR	
Ethical application amendment 2021-03487	
193 EUR	
New Zealand reimbursment (200\$/patient)	1650
EUR	
New Zealand reimbursment (200\$/patient)	1658
EUR	
Total	7382
EUR (76 504 SEK)	

How will your findings be presented?

Publication in journal

Presentation

Was your paper published? Indicate journal and acceptance date

Not published or submitted

Presentation – note meeting organisation and date

The ongoing study will be presented at the ESC-congress in Ghent May 2022 and at the FIAPAC in Riga Sep 2022.

Please let us know whether having a mentor has been helpful or not

Dr Cameron has been a great resource in the study planning as well as in the management of the ongoing study

Full Name

Karin Brandell

Date

Thursday, May 5, 2022

Questions? ESC Central Office: info@escrh.eu

Type a question

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