Thursday, October 21, 2021

Interim report

Date of sending out the form:
Tuesday, October 19, 2021

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

Initial funding (part of the grant received already) in euro:
7125

Final amount to be paid by ESC (in euro):
2375

Project number:
P-2019-A-03

Allocated mentor:
S. Cameron

Date project actually started:
Friday, February 1, 2019

Planned date of completion:
Tuesday, August 1, 2023

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?
Delayed recruitment start due to regulatory issues with amendements to etichal comittee and application to medical product agency

Slow recrutiment at start due to logistical problems at a few sites because these patients need to be informed already on the telephone and priority to the clinic so they can be evaluated before there is an IUP visible on ultrasound

Covid19 pandemic has affected most of the sites, for example Edinburgh were they have started telemedicine for patients and therefore not able to recruit patients to VEMA.
Other sites have had to minimize visits for patients and therefore not included patients during the parts of 2020/2021 or have had longer waiting time at the clinic so fewer patients are evaluated before 6 weeks of gestation (inclusion criteria)

We have increasing the recruitment period to 4 years (+ 6 months for analyzing data and manuscript writing) and added new sites to compensate for this.

News sites added:
Auckland, NZ
New South Wales, AU
Bergen, Norway
Nepal (4 sites)
Copenhagen, Denmark
Södertälje, Sweden

Have you discussed the project status and any problems with your Mentor?

Yes

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

494 patients recruited. No interim study planned.
Data Safety Monitoring Board review in Sept 2021 included data on:

4 ectopics, all in VEMA (intervention)-group, 1 ruptured but after diagnosis and start of methotrexate-treatment.

A total of 6 SAE
(the 4 ectopics as they were treated as in-patients and 1 bleeding after failed abortion, 1 laparoscopy for suspected ectopic but turned out to be an IUP after surgical evacuation)

Pain equal in both groups
VAS >8 Standard (control) 6.5%, VEMA (intervention) 5.4%

Conclusion from DSMB was that there is no reason to prematurely terminate the study at this point. They recommend increase in recruitment pace.

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

Amendment to ethical application 2000 SEK = 199 EUR
New Zealand 10 patients recruited 200 USD/patient = 17098 SEK = 1705 EUR
Indirect expense 4321 SEK = 431 EUR

Full Name

Karin Brandell

Date

Tuesday, October 19, 2021

Questions? ESC Central Office: info@escrh.eu / Tel. 0032 2 582 08 52

Once received and assessed, you will be contacted regarding the final payment.

Type a question

info@escrh.eu