Final report form for a granted project

ESC Central Office only

Date of sending the form: Aug 6, 2016

Contact person/applicant: Kristina Gemzell Danielsson

Country: Sweden

Email: Kristina.gemzell@ki.se

Title of the granted project: Post abortion contraception - Quick start of Nexplanon in medical abortion. A randomized controlled trial

Amount granted by the ESC (in euro): 7557

Project number: P-2013-A-04 Allocated mentor: None assigned

Your final report

Date project actually started: October 13 2013
Date of completion: October 17 2015 (patient recruitment completed)

Please provide:

• A report of your findings and data.
• A final detailed budget on how much you have spent. Was any money not spent? Receipts may be requested.
  o How will your findings be presented?
  o Published paper – indicate journal and acceptance date
  o Presentation – note meeting organisation and date
  o Other – please state
• Add any other information you feel we should have.
Final report on the project;

Post abortion contraception-Quickstart with Nexplanon at medical abortion.

The objective of the project was to investigate the efficacy of medical abortion followed by either immediate or delayed insertion of an etonogestrel releasing contraceptive implant to address the theoretical concern that an interaction between mifepristone and the progestin could affect the efficacy of medical abortion.

Women with gestations below 64 days opting for an contraceptive implant post medical abortion were randomized to insertion at the time for mifepristone intake (immediate) or at follow up two to three weeks later (standard care). An equivalence design was used due to advantages for women such as less visits to the clinic with immediate insertion. Primary outcome was efficacy of medical abortion defined as complete abortion without need for vacuum aspiration. Secondary outcomes were safety, insertion rates and acceptability.

Efficacy of medical abortion was 259/275 (94.2%) in the immediate insertion group and 239/249 (96%) in the routine insertion group with a risk difference of 1.8% (95% confidence interval -0.4% to 4.1%), which was within the ±5% margin of equivalence. Insertion rate was 275/277 (98.9%) in the immediate group compared to 187/261 (71.6%) women in the routine group (p<0.001). At the six month follow 2/277 (0.8%) women in the immediate group had become pregnant compared to 10/261 (3.8%) in the routine group, p=0.018.

Based on the results we conclude that a progestin releasing contraceptive implant inserted on the day of mifepristone maintained efficacy and safety of the medical abortion equivalent to routine insertion, while increasing insertion rates, and reducing subsequent unintended pregnancy and abortion.

The study has been completed with regard to the main outcome and the final one-year follow-up is on-going. Results were presented at the ESCRH conference in Basel in 2016. As soon as the one year follow up and analyses are completed a final manuscript will be submitted for publication.
Budget

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<tr>
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<th>EUR</th>
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<tbody>
<tr>
<td>Grant total</td>
<td>7557</td>
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<tr>
<td>Part of salary for study nurse</td>
<td>3557</td>
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<tr>
<td>Data base</td>
<td>1946</td>
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<td>Ethics application</td>
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<td>TOTAL</td>
<td>7557</td>
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Excess costs have been covered by the applicant. The cost for drugs for medical abortion and implants was covered by the participating clinics.

- Please let us know whether having a mentor has been helpful or not. - Not applicable
- Sign and date the form and return to the ESC Office.

Name: Kristina Gemzell Danielsson   Signed
Date: Aug 6, 2016

Please return this form (by email) to ESC Central Office at info@escrh.eu.