

Interim report

Date of sending out the form:

Friday, September 11, 2020

Contact person/applicant:

Giovanni Grandi

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Title of the granted project

A 3-D Approach to Intrauterine Contraception: Is a Ball Better than a T? A clinical randomized trial.

Amount granted by the ESC (in euro)

9500

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

7,125 Euro on 22nd November 2019.

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

9500

Project number:

P-2018-B-01

Allocated mentor:

Ambrogio Londero

Date project actually started:

Monday, December 16, 2019

Planned date of completion:

Monday, January 27, 2025

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?

Between 2/2019 and 7/2019 we have passed through Ethical Committee approval. The approval has been obtained on 3rd July 2019 by Ethical Committee Area Vasta Emilia Nord (Number 411/2019/DISP/AOUMO). After this period we have to fix the accordance between The European Society of Contraception and Reproductive Health and Azienda Ospedaliero-Universitaria of Modena, obtained on 1st of August 2019. The main problems encountered during the first months of recruitment are related to the recent pandemic caused by SARS-CoV-2. This health emergency limits the study slowing scheduled

plans and prolonging the enrolment period.

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

No problems with our Mentor Dr. Ambrogio Londero.

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

The enrolment process started on December 16th, 2019. At the date of writing this report (August 3rd, 2020) 27 IUDs have been positioned. Most of the women participating at this study are referred from the abortion hospital service. A descriptive analysis evidence that 63% are Caucasian, with a median age of 36.8 years old; none being nulliparous. 15 women have been blinded randomised to Nova T (55.6%) and 12 women to IUB (44.4%).

Through written questionnaires we compared the operator's difficulty and the discomfort caused by positioning the two different IUDs. We evaluated the pain felt by the woman by a VAS of 100 mm. The preliminary results show that the pain is worse with IUB than with Nova T. The medium pain at speculum placement is 19.3 mm with Nova T and 24.5 with IUB mm; the medium pain at IUD placement is 26.4 mm with Nova T and 27.3 mm with IUB; the medium pain felt 5 minutes after IUD placement is 8.6 mm with Nova T and 10.9 mm with IUB.

The preliminary results considering complexity in positioning the IUDs by the operator are obtained through a written questionnaire that assigns a score from 1 to 5 based on the difficulty. At the moment the procedure with the IUB seems to be more difficult than for the Nova T: the speculum placement difficulty is 2.0 with Nova T and 1.6 with IUB; the difficulty to dilate is 1.5 with Nova T and 1.4 with IUB; the pain caused to the woman is 2.6 with Nova T and 1.7 with IUB and the pain after 5 minutes is 1.7 with Nova T, and 1.4 with IUB; the vagal reaction caused by the IUDs placement is 1.2 with Nova T and 1.3 with IUB). The results about the quality of life (SF36), the quality of sexual life (FSFI), the general satisfaction and the bleeding and pelvic pain profile are still in progress.

During these first months 4 adverse events are reported, 2 regarding Nova T and 2 concerning IUB. A woman carrying Nova T after 28 days asked for removal for general dissatisfaction due to continuous pelvic pain; at ultrasound check after 28 days from the placement of a Nova T we had to remove it because it was dislocated. A woman carrying IUB after 15 days asked for removal for general dissatisfaction likely due to menopausal symptoms; an IUB was spontaneously expelled 32 days after placement.

In conclusion, at the date of writing this report 27 women have been placed in, 23 still have a IUD, 19 of which are waiting the control 1 year after insertion, and 4 of which are waiting the control after 1 month.

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

4400 Euros: Costs of the 70 IUDs (35 IUB and 35 NovaT 380), costs for visits and materials, print of questionnaires, costs for data manager for the large database collection, costs for Ethical Committee process.

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

Nothing to add.

Full Name

Giovanni Grandi

Date

Friday, September 11, 2020

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

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