Friday, August 13, 2021

Final report form

Date of sending out the form:

Wednesday, August 11, 2021

Contact person/applicant:

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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

Project number:

P-2018-B-01

Allocated mentor:

A. Londero

Date project actually started:

Monday, December 16, 2019

Date of completion:

Monday, January 27, 2025

Please provide a report of your findings and data.

The enrolment process started on December 16th, 2019. In this final report of the study we have reported data up to 10th August 2021. However, the study is still ongoing and it will finish probably in 2025 (as for initial protocol). We have enrolled a total of 62 patients, but 2 of them was not randomized for lost after first visit. Thus in total we have randomized 60 patients, of them n=30 in IUB group and n=30 in Nova T 380 group. Most of these patients were sent to us by the abortion service (n=45, 75%) and the other (n=15, 25%) were

women requesting contraception. The basal questionnaire responses were similar between groups, both for quality of life SF 36 (for IUB 79.1 ± 12.6 vs. for Nova T 380 76.0 ± 14.5, p value=0.38) and of sexual life FSFI (for IUB 24.6 ± 8.3 vs. for Nova T 380 27.0 ± 7.6, p value=0.27). At visit 2 (IUD insertion) the endometrial thickness was comparable between groups (for IUB 7.5 ± 4.7 mm vs. for Nova T 380 6.4 ± 3.2 mm, p value= 0.31), evidencing a similar menstrual phase. In questionnaires completed by the patient related to the pain felt during the procedure of placement there were no difference between groups (p value=0.87). In questionnaire completed by the physician, instead, we observed statistically significant difference between groups about the pain that it seems to have given to the patient during the insertion by the operator, that resulted minor in IUB group (for IUB 1.5 ± 0.9 points vs. for Nova T 380 2.3 ± 1.0 points, p value= 0.0015). At the time of insertion, 41/60 devices (68.3%) were located on the uterine fundus, 17/60 (28.3%) was located within 1 cm from the fundus and only 2/60 (3.3%) devices over 1 cm. The mean of distance of devices from uterine fundus at visit 2 was comparable between groups (p value= 0.59). At visit 3 were evaluated a total of 56 patients (27 Nova T and 29 IUB) because 2 women were lost to follow up (3.3%) and 2 women (3.3%) are still during the first month of use (1 Nova T 380 and 1 IUB). A total of 4 IUD (3 IUB and 1 Nova T 380) were removed because misplaced and 2 IUD (1 IUB and 1 Nova T 380) upon request of the patients. Nova T 380 was removed for dissatisfaction with the treatment (0/10) due to constant pelvic pain after placement and increase in bleeding intensity; IUB was removed for other reasons. Another IUB was spontaneous expelled during the first month of use. In total 51 women (51/58, 87.9%) are still using the IUD that is well positioned after visit 3. The rate of expulsion and severe dislocation requiring removal, despite being clinically different and showing a certain trend (4/29, 13.8% for IUB vs. 1/27, 3.7% for Nova T 380), was not statistically significant between groups (p value=0.18), as well as the overall removal rate, considering also women who asked to stop treatment (5/29, 17.2% for IUB vs. 2/27, 7.4% for Nova T 380; p value=0.27). We observed that women with IUB removed for dislocation or spontaneously expelled had a higher uterine volume in comparison to ongoing women (145,311 ± 48,300 mm^3 for IUB expelled or removed vs. 88,740 ± 36,892 mm3 in ongoing women; p value=0.014). In general, we observed that uterine volume was directly related with the migration of the device (position at visit 3 - position at visit 2 in mm) from the uterine fundus at first follow up, as

showed in Figure 18. We recorded a slight migration of the device from the uterine fundus both with IUB and Nova T 380 after 1 month of use: the distance from fundus from a mean of 1.8 ± 3.9 mm at the time of placement increased to a mean of 6.4 ± 11.3 mm after 1 month (Figure 19). The satisfaction with treatment after 1 month of use was in general very high and similar between groups (8.7 ± 1.6 points for IUB vs. 8.4 ± 2.2 points for Nova T 380, p value= 0.59), with a mean of 8.5 ± 1.9 points in a range 0 – 10 points. The pelvic pain (total and mean) during the first month of use, evaluated on a basis of 5 days, of 10 days and for all 30 days obtained by the menstrual diaries, was similar between groups and not statistically significant. In the first month after placement, we observed instead significant difference in the bleeding intensity that resulted higher in IUB group, especially in the total evaluation at 30 days (for IUB 26.3 ± 7.7 vs. for Nova T 380 20.6 ± 9.3; p value=0.03*). The difference in bleeding intensity (total and mean) are showed in Figure 24 - 25. In both groups, there were no significant changes in quality of life (SF 36) and of sexual life (FSFI) after 1 month of use.

To the present we performed a total of 17 visits at 1 year (visit 4) after placement (8 IUB and 9 Nova T 380). 1 woman was lost to follow up after visit 3. The satisfaction with the treatment after 1 year of use was still very high with a mean of 8.3 ± 2.5 points in a range 0 - 10 points and it was similar between groups (8.5 ± 1.5 points for IUB vs. 8.1 ± 3.1 points for Nova T 380; p value=0.75). The quality of sexual life (FSFI) was still good in both groups with a mean from 25.9 ± 8.0 to 26.4 ± 6.7 after 1 year of use, with no significant difference between IUB and Nova T 380 (p value=0.49). The quality of life (SF36) also remained high, despite a slight decrease from baseline values from a mean of 77.5 ± 13.6 to 73.3 ± 18.6. Between groups there were no significant changes (p value=0.75). In general women reported a lengthening of the duration of the menstrual cycle compared to the usual one before insertion of the IUD and a slight increase in bleeding intensity. However, both in the bleeding pattern (duration, intensity, spotting) and pelvic pain, evaluated with daily diary during the first year of use, there was no significant difference between groups (p value > 0.05). At visit 4 we performed 3 IUD removals (3/17, 17.6%) upon request of the patient (2 IUB and 1 Nova T 380). 1 Nova T 380 was removed for dissatisfaction with the treatment (0/10) due to recurrent episodes of cystitis (6 after placement); 2 IUBs were removed for heavy menstrual bleedings with episode of anaemia. One of these was severe and was treated with blood transfusion and iron supplementation.

To the present 47/57 (82.5%) patients are still using IUD that is well positioned (23/30 patients, 76.7% in IUB group vs. 24/27 patients, 88.9% in Nova T 380 group; p value=0.22) with a mean

follow up of 7.7 months ± 4.9 in a range 1 – 16. The satisfaction with treatment continues to be high with a mean of 8.7 ± 1.8 points in a range 0 - 10, with no significant difference between groups (8.2 ± 2.3 in IUB group vs. 9 ± 0.9 in Nova T 380 group; p value=0.23), as reported in Figure 31. From the beginning of the study a total of 10/60 IUD (16.7%) were removed or expelled: 4 IUD were removed for dislocation at visit 3 (3 IUB and 1 Nova T 380), 1 IUB was spontaneously expelled during the first month of use and 5 IUD were removed upon request of patients (3 IUB and 2 Nova T 380), 2 at visit 3 and 3 at visit 4. 3/60 patients (5%) were lost to follow up (2 women at visit 3 and 1 woman at visit 4 in Nova T 380 group).
These preliminary data will be presented as an abstract in the next 2022 Ghent 16th ESC Congress.

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

9,500 Euros:
Costs of the 70 IUDs (35 IUB and 35 NovaT 380): 2,100 Euro
Costs for visits and materials: 2,500 Euro just spent + 1,300 Euro to spend before study completion
Print of questionnaires: 100 Euro
Costs for data manager for the large database collection: 1,000 Euro
Costs for congress expenses and travels: 1,500 Euro
Costs for Ethical Committee process: 1,000 Euro

How will your findings be presented?

Publication in journal | Presentation

Was your paper published? Indicate journal and acceptance date

No, it is still ongoing. We are planning to perform two separate submissions (according to different follow-up periods) to European Journal of Contraception and Reproductive HealthCare.

Presentation – note meeting organisation and date

These preliminary data will be presented as an abstract in the next Ghent 16th ESC Congress in May 2022.

Add any other information you feel we should have

The main problems encountered during the recruitment of this RCT were related to the recent

pandemic caused by SARS-CoV-2. This health emergency limited the study slowing scheduled plans and prolonging a bit the enrolment period. However, we are very satisfied with the conduct of the study despite the pandemic.

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

No problems with our Mentor Dr. Ambrogio Londero. However, we are conducting the study with our own strength.

Full Name

Giovanni Grandi

Date

Wednesday, August 11, 2021

Questions? ESC Central Office: info@escrh.eu

Type a question

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