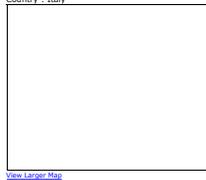


Submission Date
2018-11-04 11:01:17

Name of applicant
Giovanni Grandi

Job title
MD

Address
Street Address : Via del Pozzo 71
Street Address Line 2 :
City : Modena
State / Province : Italy
Postal / Zip Code : 41124
Country : Italy



[View Larger Map](#)

Phone Number
(+39348) 5459749

E-mail
giovanni.grandi@unimore.it

A short CV of the applicant (or the principal investigator) should be provided here. (Max 250 words)

Giovanni Grandi was born in Modena (Italy) and he graduated with honors in Medicine and Surgery in the University of the same city. He is presently an Associate Researcher for the Department of Medical and Surgical Sciences for Children and Adults of the University of Modena and Reggio Emilia (Italy), lending clinical activity as gynecologist in the Department of Obstetrics and Gynecology of the Azienda Ospedaliero-Universitaria Policlinico di Modena (Italy). His main research topics are hormonal contraception, gynecological endocrinology and the prevention of gynecological cancers and oncogenetic counseling. He has published many papers as first author in main peer-reviewed Journals in the last years, being also constantly invited as ad hoc reviewer. In 2016 and 2017 he was elected as best reviewer for Obstetrics and Gynecology (The Green Journal), the Onkoin Journal with the highest Impact Factor. He was elected member of the Expert Group on Sexual Medicine and Sex Education of The European Society of Contraception and Reproductive Health in the period 2014-2016. Since 2016 he is the Editor of The European Journal of Contraception and Reproductive HealthCare. He is the director of the Service of Contraception of the University Hospital Policlinico di Modena since 2017.

Submission date of this form
Sunday, November 04, 2018

Is the person responsible for the project different to the person named in box A
No

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

Please provide a comprehensive description of your project. The application will be assessed under the following headings: Background and hypothesis; Specific aims and objectives; a Needs Analysis with evidence of unmet need and Innovation; Approach and Methodology; ie numbers recruited, ethical approval, inclusion & exclusion criteria; Expected outcomes; Impact it will or may have in the field of contraception, sexual and reproductive health; Feasibility (1000 words)

Background
The field of long-acting reversible contraceptives (LARCs) in general and IUDs in particular has seen few innovations in the last few decades. The classical IUDs are T shaped or U frame, and only a few are different (thread, rings and others); however, when deployed in the uterus, they all take a two-dimensional shape. Four years ago a new intrauterine device was invented by Baram I et al. (1): the intrauterine ball (IUB). The SCu300A IUB is a copper intrauterine device made by Nitinol and 17 copper pearls that, upon insertion in the uterus, takes a three-dimensional spherical form. Due to its form and deployment process, the IUB is expected to reduce perforation, malposition and expulsion rates and may also reduce dysmenorrhea and menorrhagia. The IUB is intended to have a lifetime of 5 years. This system has also intrigued major medical Journals: a 3-D approach to intrauterine contraception is better than a T? (see <https://www.jwatch.org/na33359/2014/01/23/2-0-approach-intrauterine-contraception-ball-better-t>). However, no published literature about its comparison with classical T shaped IUD is available today in the literature. For these reasons, we have decided to conduct a well designed clinical randomized comparative trial about the two types of IUDs in our University Hospital Service for Contraception.

Hypothesis
The ideas beyond its possible improvements of IUB in comparison to tradition IUDs are:
- The IUB is inserted by an insertion tube with an outer diameter of 3,2 mm, smaller than traditional copper IUDs.
- During insertion, the tip of the IUB turns 180° as it exits the insertion tube, away from the uterine fundus, thus reducing the risk of fundal perforation during insertion. This attribute simplifies the process for operators with less experience in IUD insertion who are more prone to uterine perforation.
- The diameter of the IUB (12±2 mm) is ~14%–25% smaller than each arm of current T-shaped IUDs. The smaller size is expected to reduce irritation to the uterine wall while being large enough not to clear the cervix internal os, thus nullifying the probability of expulsion.
- The IUB lacks sharp edges, thus possibly preventing uterine wall irritation and distortion.
- Malpositioning within the uterine cavity is prevented through the spherical shape of the IUB.

Aims & objectives
To evaluate the outcomes shown below between a IUB and a Nova T 380 IUD in a 12-months follow up.
Methodology
Women who requested the use of intrauterine device for contraception in the service of Contraception of Policlinico University Hospital of Modena, directed by Giovanni Grandi M.D., will be randomized to IUB (n=35) vs. Nova T 380 (n=35). Exclusion criteria will be contraindications to IUD use. We will ask the ethical approval by the Comitato Etico dell'Area Vasta Emilia Nord, before the start of recruitment. The recruitment could start in January 2019 ending in March (3 months), with the final follow up visits for March 2020.

Results and expected outcome
Outcomes evaluated
35 subjects per group, Baseline visit, 2 months visit, 12 months visit (end of study)

Visit 1 (Baseline)
- Basal features
- Transvaginal US
- Give bleeding and pain diary
- Pain and time at insertion evaluation
- Questionnaires of mood, quality of life and sexual life

Visit 2 (2 months)
- Transvaginal US, malpositioning??
- Collect bleeding and pain diary
- Questionnaires of mood and quality of life, satisfaction and sexual life
- Collect adverse effects, Perforations? Expulsions? Infections?

Visit 3 (12 months)
- Transvaginal US, malpositioning??
- Collect bleeding and pain diary
- Questionnaires of mood and quality of life, satisfaction and sexual life
- Collect adverse effects, Perforations? Expulsions? Infections?
- What impact will or may this project have in the field of SRH?

Although the IUB design is intriguing, we still need to learn how the IUB's performance (including rates of infection, perforation, expulsion, device malposition, and continuation as well as insertion pain and impact on bleeding) compares with that of existing IUDs. The introduction of better and well tolerated devices would encourage the use of LARCs, reducing the number of unintended pregnancies.
This RCT will be completely independent by pharmaceutical industries interests.

Reference:

1) Baram I et al, Contraception. 2014;89(2):139-41.

Timeline: When will it start / finish? (Max 20 words)
Start January 2019-End March 2020

Where will it take place – country / town, establishment? (Max 20 words)
Modena, Italy - University Hospital of Modena, Policlinico - Service for Contraception

Sector in the area of contraception, sexual and reproductive health:
Intrauterine device research, LARCs research

Is it a 'new' project?
Yes

Do you foresee any reasons (political, climatic, etc) why this project may be adversely affected? (Max 20 words)
None

How much will this project cost?
9923

How much are you requesting from ESC?
9923

Are there other partners or organisations supporting this same project?
No

Have you already obtained any funding?
No

Are you still awaiting a response towards this project? (Give details in the table below)
No

Budget

List each Item required for this project	Amount requested from ESC	Amount requested from additional partner	Name of partner	Any Comments
Cost of IUDs	7193	0		In Italy Nova T 380 costs 55.5 Eur, IUB costs 150 Eur
Medical Staffing for the visits	2730	0		13 Euros per visit for the staff, 3 visits for subject, 3x70=210 visits
		0		

Total amount requested from ESC
9923

Total amount requested from partner(s)
0

Add any additional information here

This RCT will be completely independent by pharmaceutical industries interests.
Giovanni Grandi and his co-researchers have no conflicts of interests to declare with the manufacturer of IUB (Ocon Medical Ltd) and will conduct the study in full scientific freedom.

The ESC may not be in a position to fully fund all applications; you must indicate whether / how part funding may impact your project. (Max 100 words)
The cost of IUDs (7193 Euros). I could try to ask for other independent funding for the cost of the staff.

Who will oversee the budget & keep accounts? Provide name, title, contact number and email address

Professor Fabio Facchinetti, +39059422 2665, fabio.facchinetti@unimore.it, The Chief of my Department, University Hospital Policlinico di Modena, University of Modena and Reggio Emilia

If you or your department has received funding from ESC for a project or course before, please give details of the date of funding, contact person and title of project or course.
No funds before.

I/We, as responsible agents for this project, agree to the following 10 points:

I/We agree that all monies will be spent appropriately	yes
I/We agree to work with the nominated Mentor	yes
I/We agree to advise you at the earliest time if this project is delayed or cannot be completed	yes

I/We agree to provide an interim report(s) part way through the project and a final report to the ESC within 6 months of the end of the project.	✓
I/We agree to provide the ESC with an interim budget(s) and a detailed budget at the end of the project. NOTE funding will be awarded in stages and will be dependent on appropriate reporting.	✓
I/We agree to provide receipts for monies spent if requested.	✓
I/We agree that if we need to make any significant changes to the duration, contents or funding of the project after it has been awarded, I/we will advise the nominated mentor.	✓
I/We agree that any unspent money will be returned to the ESC	✓
I/We (the applicant) agree to acknowledge the ESC as a donor in any publications, submission of abstracts and oral communications resulting from this project. Please inform the ESC Office where and when the data is to be presented and/or published and note that ideally any manuscript should be sent to the ESC Journal in the first instance.	✓
I/We agree to remain fully paid up ESC member(s) until the final grant report is submitted	✓

Full Name
Giovanni Grandi

Date
Sunday, November 04, 2018