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Multicentre study comparing two endometrial ablation techniques in the office: bipolar endometrial ablation versus balloon endometrial ablation

Submission date
07/01/2013

Recruitment status
No longer recruiting

Registration date
11/02/2013

Overall study status
Completed

Last Edited
11/02/2013

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Excessive menstrual bleeding, or menorrhagia, is a significant health problem in women in reproductive age. It can cause anemia and reduce their quality of life. We want to compare the effectiveness and acceptability of two second-generation endometrial ablation [is a medical procedure that is used to remove (ablate) or destroy the endometrial lining of a uterus] techniques, bipolar radiofrequency endometrial ablation and balloon ablation in the treatment of menorrhagia.

Who can participate?
This study aims to recruit about 104 women with menorrhagia who want to undergo an endometrial ablation.

What does the study involve?
Over a period of about three years participants will be undergo an endometrial ablation randomly allocated to bipolar endometrial ablation or balloon ablation in the outpatient clinic. Visual analogue scales will be used to measure pain when dilating the cervix, during the endometrial ablation, and at 1,4,12 and 24 hours after the procedure. Follow-up visits at the outpatient clinic or by telephone will be at 6 weeks, 6 months and 12 months after the initial treatment. At each follow up visit, duration of menstruation, presence of dysmenorrhea and clots will be registered. Patients will also complete a pictorial chart, and will express their satisfaction about the treatment result.
At the end of the study, we will compare the amount of women with amenorrhea. Other outcome measures will be painscores, reduction in bleeding, patient satisfaction and re-interventions.

What are the possible benefits and risks of participating?
These are women who already want an endometrial ablation to be performed for their menorrhagia. The identifiable risks associated with the use of the Novasure and/or Thermablate

ablation as well as participation in this study is as follows: hemorrhage, perforated uterine wall, lacerated cervical canal, cervical stenosis, urinary tract/vaginal infection, hematometra, thermal damage, endometritis, abdominal surgery to repair a possible perforation and post-coital bleeding. Other clinical events include pelvic cramping, vaginal discharge, nausea/vomiting, post ablation tubal sterilization syndrome and pregnancy following ablation, which may be dangerous to the mother and fetus. All risks are possible and the chance of their occurrence is low. There is also the risk that the surgery may not be effective or the patient may not be able to be treated because of obstructions within the cavity, an unusual cavity shape or an insufficient cornu-to-cornu width. All adverse events or complications, device related or not, will be recorded and reported.

Where is the study run from?
The study has been set up by the department of Obstetrics & Gynecology in the Maxima Medical Centre in Veldhoven, The Netherlands. Other participating hospitals are the TweeSteden Kliniek in Tilburg and the ZuidOostKliniek in Amsterdam, the Netherlands.

When is the study starting and how long is it expected to run for?
Recruitment started in March 2009 and we expect it to run for about three years. Participants were enrolled on the study for a period of one year.

Who is funding the study?
Maxima Medical Centre (Netherlands) - Department of Obstetrics & Gynecology

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Bipolar radiofrequency endometrial ablation versus balloon endometrial ablation in women with dysfunctional uterine bleeding in the office: a multi-centre randomized controlled trial

Acronym
NOTE

Study objectives
NOTE [NOvasure versus ThErmablate]

The balloon endometrial ablation (Thermablate) will give a 30% amenorrhea rate and will be acceptable to undergo with only local anesthesia. The bipolar radiofrequency endometrial ablation (Novasure) will be the gold standard.

The null hypothesis is that there is no difference in amenorrhea rate between both groups.

Ablation techniques in the office: The endometrial ablation procedures were performed in the outpatient clinic with local anesthesia (paracervical block) and not in the operating room.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee Maxima Medical Centre, Veldhoven, February 2009, Ref. : 813

Primary study design
Interventional

Study design
Multi-centre double-blind randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Endometrial ablation in women with menorrhagia

Interventions
Bipolar endometrial ablation (NovaSure) versus balloon endometrial ablation (Thermablate).

The total duration of treatment was about 5 to 45 minutes, mean: 11 minutes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The number of women with amenorrhea measured at 6 weeks, 6 months and 12 months after treatment, scored (zero) on a pictorial chart menstruation score.

Key secondary outcome(s)

1. Painscores: Visual analogue scales were used to measure pain during the procedure when dilating the cervix, during the endometrial ablation, and at 1, 4, 12 and 24 hours after the procedure
2. Reduction in menstrual bleeding : measured by a pictorial chart score at baseline and at each follow up visit at 6 weeks, 6 months and 12 months after the endometrial ablation
3. Patient satisfaction : asked at each follow up visit at 6 weeks, 6 months and 12 months after the procedure (completely satisfied, satisfied, doubtful, unsatisfied)
4. Re-interventions: measured at 6 weeks, 6 months and12 months after the endometrial ablation
5. Quality of life: measured with a Shaw questionnaire (multi attribute utility menstruation scale) at baseline, and each follow up visit at 6 weeks, 6 months and 12 months follow up

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Women (aged 34 to 55 years) with menorrhagia (> 150 points on Higham pictorial chart score)
2. Normal uterine cavity (confirmed by saline infusion sonography or hysteroscopy)
3. Normal Pap smear
4. A premenopausal follicular stimulating hormone (FSH)-level of less than 40 IU/l

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Presence of coagulopathies
2. Use of anti-coagulants
3. A desire to preserve fertility
4. Prior uterine surgery, other than low segment Caesarean section
5. Suspected or confirmed uterine malignancy
6. Intra cavitairy pathology, except polyps < 1cm

Date of first enrolment
01/03/2009

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
De Run 4600
Veldhoven
Netherlands
5500 MB

Sponsor information

Organisation
Maxima Medical Center (Netherlands)

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maxima Medical Centre (Netherlands) - Department of Obstetrics & Gynecology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration