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Endometrial tissue ablation: a clinical trial

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2010	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Demonstrate that the HydroThermAblation procedure is equally effective compared to the Novasure procedure in achieving patent satisfaction at twelve months post-treatment for menorrhagia secondary to DUB.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dysfunctional uterine bleeding

Interventions
Hydrothermablator (HTA) System versus ablation with Novasure

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patients satisfaction:
At each follow up visit/telephone call patients satisfaction was noted. Patients can express their level satisfaction by using - completely satisfied, satisfied, doubtful satisfied or not satisfied.
It is also noted if any kind of reintervention is performed, such as the use of oral contraceptives or surgery.

Secondary outcome measures
1. Quality of life: all patients are asked to complete quality of life questionnaires at baseline, at two days, six weeks, three months, six months and twelve months after surgery. We evaluate quality of life with the medical outcomes study SF 36, the Rotterdam symptom checklist and a structured clinical history questionnaire.
2. Amennorhoea: at each follow up visit/ telephone call duration of menstruation, dysmennorhoea and presence of clots are registered. Patients also complete a pictorial chart.

Overall study start date
01/03/2005

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Refractory menorrhagia with no definable organic cause (dysfunctional uterine bleeding).
2. Age over 25 years old
3. Uterine sound measurement of 6.0 - 12 cm (external os to internal fundus).
4. Failed, contraindicated or intolerance to conservative (medical) therapy.
5. Menstrual Diary:
A minimum PBLAC score of > 150 for 1 month. Intracavitary pathology, such as type 2 fibromas and small polyps (≤ 2cm), confirmed by hysteroscopy or Saline Infused Sonography (SIS)

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
160

Key exclusion criteria
1. Presence of bacteremia, sepsis, or other active systemic infection
2. Active or recurrent chronic pelvic inflammatory disease
3. Patients with documented coagulopathies
4. Symptomatic endometriosis
5. Prior uterine surgery (except low segment cesarean section) which interrupts the integrity of the uterine wall e.g.transmural myomectomy or classical cesarean section. Prior endometrial ablations.
6. Patients on medications that could thin the myometrial muscle, such as long-term steroid use.
7. Patients on anticoagulants.
8. Desire to have children or to preserve fertility
9. Patients currently on hormonal birth control therapy or unwilling to use a non-hormonal birth control post-ablation.

10. Abnormal/Obstructed Cavity as confirmed by hysterscopy, Saline Infused Sonography (SIS) or HSG. Specifically: Septate or bicornuate uterus or other congenital malformation of the uterine cavity.

Date of first enrolment
01/03/2005

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Maxima Medisch Centrum
Veldhoven
Netherlands
5500 MB

Sponsor information

Organisation
Maxima Medisch Centrum (The Netherlands)

Sponsor details
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info@mmc.nl

Sponsor type
Hospital/treatment centre

Website
http://www.mmc.nl/

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Máxima Medisch Centrum (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No