Endometrial tissue ablation: a clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22028

Source
NTR

Brief title
N/A

Health condition

Dysfunctional uterine bleeding

Sponsors and support

Primary sponsor: Channa Klein; J.Kleijn@mmc.nl
Source(s) of monetary or material Support: NONE

Intervention

Outcome measures

Primary outcome

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¡¯s also noted if any kind of reintervention is performed, such as the use of oral contraceptives or surgery.

Secondary outcome

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.

Study description

Background summary

Objective:

To compare patient satisfaction amd health-related quality of life (HRQoL) after bipolar radio frequency ablation and ablation with a HYDROTHERMABLATOR (HTA) SYSTEM in women with dysfunctional uterine bleeding.

Design:

Randomized clinical trial.

Setting:

Teaching hospital.

Patient(s):

Women suffering from dysfunctional uterine bleeding.

Intervention(s):

Bipolar radio frequency ablation and ablation with aHYDROTHERMABLATOR (HTA) SYSTEM .

Main outcome measure(s):

Patients will be asked to report treatment satisfaction complete HRQoL questionnaires at baseline, and at 3 months, 6 months, and 12 months after surgery. The questionnaires contain the medical outcomes study Short-Form 36 (SF-36) and a structured clinical history questionnaire.

Study objective

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.

Study design

N/A

Intervention

Hydrothermablator (HTA) system versus ablation with novasure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Refractory menorrhagia with no definable organic cause (dysfunctional uterine bleeding);

2. Ages over 25 years old;

3. Uterine sound measurement of 6.0 ¨C 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;

6. Intracavitary pathology, such as type 2 fibromas and small polyps (¡Ü 2cm), confirmed by hysteroscopy or Saline Infused Sonography (SIS).

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;

6. Prior endometrial ablations;

7. Patients on medications that could thin the myometrial muscle, such as long-term steroid use;

8. Patients on anticoagulants;

9. Desire to have children or to preserve fertility;

10. Patients currently on hormonal birth control therapy or unwilling to use a non-hormonal birth control post-ablation;

11. Abnormal/Obstructed Cavity as confirmed by hysterscopy, Saline Infused Sonography

(SIS) or HSG. Specifically:

11.1 Septate or bicornuate uterus or other congenital malformation of the uterine cavity.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2005
Enrollment:	160
Type:	Actual

Ethics review

Positive opinion

Date:	29-07-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL66
NTR-old	NTR98
Other	: N/A
ISRCTN	ISRCTN23845359

Study results

Summary results
N/A