A RANDOMISED CONTROLLED TRIAL COMPARING BALLOON ENDOMETRIAL ABLATION (THERMABLATE) VERSUS BIPOLAR ENDOMETRIAL ABLATION (NOVASURE) IN THE OUTPATIENT CLINIC WITH LOCAL ANESTHESIA

Published: 25-06-2009
Last updated: 11-05-2024

The purpose of the study is to evaluate the effectiveness and acceptability of the hot fluid balloon endometrial Thermablate ablation system compared with the Bipolar RF Novasure ablation treatment performed in an outpatient setting in eliminating...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON34001

Source
ToetsingOnline

Brief title
Thermablate vs Novasure under local anesthesia

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
heavy menstrual bleeding; menorrhagia

Research involving

Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: gewone klinische traject

Intervention

Keyword: Endometrial ablation, Local anesthesia, Menorrhagia

Outcome measures

Primary outcome

Primary Objective Evaluate the effectiveness of Device procedure compared to

in achieving amenorrhea at twelve months post-treatment for menorrhagia

secondary to DUB

Secondary outcome

Evaluate and compare pain and acceptability scores of the hot fluid balloon

ablation (Thermablate) procedure and the Novasure Endometrial Ablation

procedure as an outpatient treatment.

Study description

Background summary

Since 1994 a lot of blind, disposable endometrial ablation devices have been developed. One of these is the Novasure ablation technique which uses RF-currency. This technique has been proven effective (Bongers 2004, Kleijn 2008). Recently this technique has been performed under local anesthesia in the outpatient clinic. The Thermablate ablation technique is relatively new on the market. It is a balloon technique with a small diameter and short treatment time. Theoretically it seems perfect for an outpatient treatment under local anesthesia.

Study objective

The purpose of the study is to evaluate the effectiveness and acceptability of the hot fluid balloon endometrial Thermablate ablation system compared with the Bipolar RF Novasure ablation treatment performed in an outpatient setting in eliminating menorrhagia secondary to dysfunctional uterine bleeding in women who no longer wish to retain fertility

Study design

RCT 1:1 randomisation

Intervention

Novasure Global endometrial ablation
Thermablate endometrial ablation

Study burden and risks

No extra risk for the patient in comparison with endometrial treatment outside the trial.

Only 25 minutes of time necessary for interview lists and the painscore

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Refractory menorraghia ;Uterine sound measurement of 6.0 - 12 cm ;Failed, contraindicated or intolerance to conservative therapy. ;Menstrual Diary A minimum score of >150 for 1 months ;Willing to undergo the treatment under local anesthesia in the outpatient clinic

Exclusion criteria

3.2.2.1 Presence of bacteremia, sepsis, or other active systemic infection;3.2.2.2 Active or recurrent chronic pelvic inflammatory disease ;3.2.2.3 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.;3.2.2.4 Desire to preserve fertility ;3.2.2.5 Abnormal/Obstructed Cavity as confirmed by hysterscopy, Saline Infused Sonography (SIS) ;3.2.2.6 Suspected or confirmed uterine malignancy or confirmed uterine malignancy within the last five years as confirmed by histology);3.2.2.7 Endometrial hyperplasia as confirmed by histology ;3.2.2.8 Unaddressed cervical dysplasia;3.2.2.9 Elevated FSH levels consistent with ovarian failure (> 40 IU/ml) ;3.2.2.10 Active sexually transmitted disease

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2009
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2009
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL22264.015.08