Endometrial tissue ablation: a clinical trial.

Gepubliceerd: 29-07-2005 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22028

Bron
NTR

Verkorte titel
N/A

Aandoening

Dysfunctional uterine bleeding

Ondersteuning

Primaire sponsor: Channa Klein; J.Kleijn@mmc.nl
Overige ondersteuning: NONE

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Hydrothermablator (HTA) system versus ablation with novasure.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2005
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A