Procedural sedation for hysteroscopic myomectomy: costeffectiveness

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Hysteroscopic myomectomies are performed in the majority of Dutch hospitals. The number of procedures for submucosal type 0 or I myomas between 1-3 cm performed in the operating room is estimated to be 3000 per year. Hysteroscopic myomectomy is...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28160

Bron
Nationaal Trial Register

Verkorte titel
PROSECCO

Aandoening

Hysteroscopy, myomas, fibroids, resection, procedural sedation, cost-effectiveness, propofol, hysteroscopische myoomresectie

Ondersteuning

Primaire sponsor: Máxima Medisch Centrum Veldhoven
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome will be the percentage of complete resections, evaluated by transvaginal

ultrasonography (TVU) (contrast sonography if TVU is inconclusive) 6 weeks postoperatively. TVU will be performed by an independent gynecologist or ultrasonographer blinded for the surgery outcome.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: In women with abnormal uterine bleeding, fibroids are a frequent finding. In case of heavy menstrual bleeding and presence of submucosal type 0 – 1 fibroids, hysteroscopic resection is the treatment of first choice, as removal of these fibroids is highly effective. Hysteroscopic myomectomy is currently usually performed in the operating theatre. A considerable reduction in costs and a higher patient satisfaction are expected when procedural sedation and analgesia with propofol (PSA) in an outpatient setting is applied. However, both safety and effectiveness – including the necessity for re-intervention due to incomplete resection – have not yet been evaluated.

Methods: This study is a multicentre randomised controlled trial with a non-inferiority design and will be performed in the Netherlands. Women > 18 years with a maximum of 3 symptomatic type 0 or 1 submucosal fibroids with a maximum diameter of 3.5 cm are eligible to participate in the trial. After informed consent, 205 women will be randomised to either hysteroscopic myomectomy using procedural sedation and analgesia with propofol in an outpatient setting or hysteroscopic myomectomy using general anaesthesia in a clinical setting in the operating theatre.
Primary outcome will be the percentage of complete resections, based on transvaginal ultrasonography 6 weeks postoperatively. Secondary outcomes are cost effectiveness, menstrual blood loss (Pictorial blood assessment chart), quality of life, pain, return to daily activities/work, hospitalization, (post)operative complications and re-interventions. Women will be followed up to one year after hysteroscopic myomectomy.

Discussion: This study may demonstrate comparable effectiveness of hysteroscopic myomectomy under procedural sedation and analgesia versus general anaesthesia in a safe and patient friendly environment, whilst achieving a significant cost reduction.

Doel van het onderzoek

Hysteroscopic myomectomies are performed in the majority of Dutch hospitals. The number of procedures for submucosal type 0 or I myomas between 1-3 cm performed in the operating room is estimated to be 3000 per year. Hysteroscopic myomectomy is currently performed in daycare under general anesthesia. A considerable cost reduction is expected when procedural sedation with propofol is applied. Procedural sedation is used for a wide variety of interventional procedures in multiple settings outside the operation room. In gynaecology, the use of procedural sedation has become more popular since technical and instrumental improvements have significantly increased the feasibility and acceptability of

hysteroscopy in outpatient settings. The shift from surgery in an operating theatre to an office-based setting and shorter hospital stay -day care versus outpatient care- are the major contributing factors to the expected cost reduction. We expect higher patient satisfaction, as both hospital stay and time-to-work are shorter and side effects such as nausea are reduced. However, both safety and effectiveness – including the necessity for re-intervention due to incomplete resection- have not yet been fully evaluated. In summary, we expect comparable effectiveness of the procedure in a safe and patient friendly environment whilst achieving a significant cost reduction.

Onderzoeksopzet

Baseline: UFS-QoL, EQ-5D-5L,PBAC score

24 hours: questionnaire on side effects nausea and vomiting, pain (NRS score), RI-10, EQ-5D-5L

2 weeks: RI-10, EQ-5D-5L

6 weeks: Transvaginal ultrasonography for assessment of completeness of resection
8 weeks: RI-10, EQ-5D-5L, PBAC score, UFS-QoL, iMCQ, iPCQ.

6 months: EQ-5D-5L, iMCQ, iPCQ

12 months: EQ-5D-5L, PBAC score, iMCQ, iPCQ, questionnaire on re-intervention

Onderzoeksproduct en/of interventie

- Procedural sedation and analgesia in an outpatient setting: According to guidelines from the Health Care Inspectorate (IGZ) and Dutch Institute for Healthcare Improvement (CBO) non-anesthesiologist administered Propofol (NAAP) sedation is given and monitored by a qualified sedation practitioner. The patient will be assessed by the sedation practitioner immediately prior to surgery on the basis of a pre-operative questionnaire. Non-invasive blood pressure, electrocardiogram and oxygen saturation are measured before vascular access is obtained. Propofol and alfentanil are used for procedural sedation.
Hysteroscopic resection is performed by an experienced surgeon by standard procedure in an office-based setting. Patients are observed after the procedure by qualified personnel and discharged as soon as all the discharge criteria are met, normally within 1 to 1.5 hours.

General anesthesia: General anesthesia can be volatile based or total intravenously, with the use of a laryngeal mask. Postoperative, patients will be observed in the recovery room and discharged home from the clinic when all the discharge criteria are met.

The way hysteroscopic resection is performed under general anesthesia does not differ from the way it is performed under procedural sedation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The following women will be included:
- A minimum age of 18 years
- A maximum of 3 symptomatic type 0 and type 1 submucosal fibroids
- A maximum diameter of 3.5 cm (as diagnosed by transvaginal ultrasonography)
- American Society of Anaesthiologists (ASA) class 1 or 2
- Sufficient knowledge of Dutch or English language to fully understand the study and complete the questionnaires

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Presence of clotting disorders
- Severe anemia (Hb under 5.0 mmol/l)
- ASA class 3 or 4

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	205
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5208
NTR-old	NTR5357
Ander register	ZonMW : 843002603

Resultaten

Samenvatting resultaten
The principal investigator will publish the results of the study in a peer reviewed medical journal as soon as appropriate.