Procedural sedation for hysteroscopic myomectomy: costeffectiveness

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28160

Source
Nationaal Trial Register

Brief title
PROSECCO

Health condition

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

Sponsors and support

Primary sponsor: Máxima Medisch Centrum Veldhoven
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes are cost effectiveness, pain, menstrual blood loss (PBAC score), quality of life as assessed by questionnaires: EuroQoL (EQ-5D-5L), Recovery Index (RI-10) and Uterine Fibroid Symptoms – Quality of Life questionnaire (UFS-QoL), return to daily activities/work, hospitalization, Medical Consumption Questionnaire (iMCQ): for cost effectiveness analysis, Productivity Cost Questionnaire (iPCQ) to assess productivity loss, (post)operative complications, re-interventions.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

- 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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2015
Enrollment:	205
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL5208
NTR-old	NTR5357
Other	ZonMW : 843002603

Study results

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