Procedural sedation for hysteroscopic myomectomy: cost effectiveness

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Is hysteroscopic resection of submucous myomas under procedural sedation with propofol (PSA) in an outpatient setting a cost-effective alternative for hysteroscopic myomectomy performed under general anesthesia in the operation room?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON50378

Source
ToetsingOnline

Brief title
Prosecco

Condition

- Reproductive neoplasms female benign
- Menstrual cycle and uterine bleeding disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
fibroids, submucosal myomas

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cost effectiveness, hysteroscopic myomectomy, procedural sedation, propofol

Outcome measures

Primary outcome

complete resection

Secondary outcome

Costs, pain, menstrual blood loss (PBAC score), quality of life, return to

daily activities/work, hospitalization, (post)operative complications,

re-interventions.

Study description

Background summary

Myomas are a frequent finding in patients with abnormal uterine bleeding. The Dutch Guideline *Heavy menstrual bleeding* recommends hysteroscopic myomectomy as treatment of first choice in case of symptomatic submucous myomas. In the current situation, patients are admitted into daycare and they are operated under general anesthesia. In the last decades, there has been a trend in hysteroscopic surgery to move from a traditional operating theatre with general anesthesia to an outpatient setting. Procedural sedation is used for a wide variety of interventional procedures in multiple settings outside the operation room. For resection of myomas, however, procedural sedation is currently not commonly used. We expect that hysteroscopic myomectomy using procedural sedation is equally effective as under general anesthesia. A significant cost reduction is expected.

Study objective

Is hysteroscopic resection of submucous myomas under procedural sedation with propofol (PSA) in an outpatient setting a cost-effective alternative for hysteroscopic myomectomy performed under general anesthesia in the operation room?

Study design

Multicenter randomised controlled trial, with a cost effective analysis alongside it.
Non-inferiority study. With 205 women randomized we have 90% power to demonstrate non-inferiority, based on an estimated 2,5% incomplete resections in both groups, with an non-inferiority upper limit of 10%, an alpha of 0.025 and a drop-out rate of 10%.

Intervention

hysteroscopic myomectomy under procedural sedation with propofol compared to hysteroscopic myomectomy under general anesthesia.

Study burden and risks

There are no additional risks involved for patients participating in this study. Procedural sedation is used for a wide variety of interventional procedures in multiple settings outside the operation room and is considered to be a safe procedure. Hysteroscopic myomectomy is an effective and safe procedure. It is performed by an experienced surgeon by standard procedure. The procedure is not influenced by the type of anesthesia used.

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

- Women with a minimum age of 18 years
- Symptomatic type 0 or I submucous myomas
- Maximum number of submucous myomas: 3
- Maximum diameter of submucous myomas: 3,5 cm
- American Society of Anesthesiologist class 1 or 2

Exclusion criteria

- Women aged under 18 years
- Inability to understand Dutch or English
- American Society of Anesthesiologist class 3 or 4
- Clotting disorders
- Severe anemia (Hb under 5.0 mmol/l)
- > 3 submucous myomas
- diameter of submucous myoma > 3,5 cm

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2016
Enrollment:	205
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-10-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	23-05-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-08-2020
Application type:	Amendment
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	NL54779.015.15