Uterine artery embolization versus hysterectomy for symptomatic adenomyosis: a case-control study

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

Summary

ID

NL-OMON55436

Source
ToetsingOnline

Brief title
QUESTA

Condition

- Reproductive neoplasms female benign
- Vascular therapeutic procedures

Synonym
Adenomyosis, endometrium in uterine wall muscle.

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Boston Scientific,Boston Scientific (eerder

Celanova)

Intervention

Keyword: Adenomyosis, Embolization, Hysterectomy

Outcome measures

Primary outcome

Primary endpoint: quality of life as measured by a combination of the World Health Organization Quality-of-Life Scale (WHOQOL-Bref) and short-form-12 (SF-12) questionnaire at 26 weeks after therapy.

Secondary outcome

The two treatments will also be compared in terms of Clinical outcomes, Recovery related outcomes, Quality of life outcomes and cost outcomes. Also imaging outcomes will be investigated at baseline in order to identify potential predictive parameters for therapy effect.

Study description

Background summary

Adenomyosis is defined as the benign invasion of endometrial stroma and glands in the myometrium, surrounded by hypertrophic and hyperplastic myometrium. Today adenomyosis still poses a gynaecological challenge. There are differences in opinion and thus differences in definition, diagnosing as well a treatment options.
Adenomyosis is frequently suspected in patients with abnormal uterine bleeding and dysmenorrhea and diagnosed in the uterine specimen of patients with presumed uterine fibroids. Due to improved quality of imaging techniques the accuracy to detect adenomyosis compared to histology has increased.
Hysterectomy is established as the final treatment option when conservative treatment fails. Case series for UAE (uterine artery embolization) in adenomyosis patients show promising results, however . A randomized controlled trial is lacking.

Study objective

This study aims to evaluate the impact of UAE on Quality of life (QOL) in comparison to hysterectomy in adenomyosis patients. A cost-effectiveness study will be part of the trial as well as a cohort hysterectomy group to clearify imaging and diagnosis of adenomyosis.

Study design

Case-control study

Protocol change
The original protocol described a randomized controlled trial where eligible patients (not changed) were randomized to either hysterectomy or UAE in a 1:2 ratio. Inclusion rates were disappointing, resulting in very low progress of the trial. Therefore a new design was chosen: a case-control design with retrospective matching (or correction of baseline variables if not identical at baseline. Although randomized data are strongest, a case control study still renders the best evidence in this field, since no comparative study has been performed so far. This protocol has been changed (with track changes) to the new design.

Intervention

UAE, performed by experienced interventional radiologists versus hysterectomy (laparoscopically, abdominally or vaginally).

Study burden and risks

Both UAE and hysterectomy are performed for symptomatic adenomyosis. There is ample experience with UAE, both for symptomatic uterine fibroids and post-partum haemorrhage. Also, adenomyosis embolization has been performed in numerous case series. A comparative study with hysterectomy has never been made with any other treatment. Therefore, this study is about efficacy and not about safety. There are no specific risks as women who are willing to conceive are excluded. The specific risks that apply to the treatment are described above (E9).

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

• Premenopausal women with symptomatic adenomyosis or dominant adenomyosis in combination with fibroids.
• Woman who are (due to complaints and non responsive former treatment strategies) eligible for hysterectomy
• No wish to conceive
• Able to understand Dutch or English language.

Exclusion criteria

• Younger than 18 years of age
• Pelvic infection/Suspicion or presence of malignancy
• Current pregnancy
• Contra-indication for angiography (such as contrast fluid allergy, coagulopathy and renal failure), when not treatable
• Deep infiltrating endometriosis requiring surgery or with risks on intestinal stenosis
• Concurrent removable submucous fibroids (Patients eligible after removal)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-11-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	27-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2021
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23586
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52652.029.15