QUality of life after Embolization vs. hySTerectomy in Adenomyosis.

Published: 17-02-2016
Last updated: 17-03-2024

This study aims to evaluate the impact of UAE on Quality of life (QOL) in comparison to hysterectomy in adenomyosis patients.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23586

Source
Nationaal Trial Register

Brief title
QUESTA trial: QUality of life after Embolization vs. hySTerectomy in Adenomyosis.

Health condition

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. Study population:Premenopausal women without the desire to conceive and who have symptomatic MRI confirmed pure adenomyosis or dominant adenomyosis in combination with fibroids.(If the deep fibroids are clearly less to the extent of adenomyosis in terms of volume we consider it dominant adenomyosis)

Sponsors and support

Primary sponsor: VU Medical Center
Source(s) of monetary or material Support: This research is funded by sponsors; however is investigator initiated. Thus: the sponsor is not involved in patient recruitment,

data analysis or manuscript preparation. Indespite of outcome the trial will be published.

Sponsors:
2015-2018: Celonova Biosciences
2019-2021: Merit medical

Intervention

Outcome measures

Primary outcome

• Quality of life:
To demonstrate non inferiority of treatment of adenomyosis with uterine artery embolization compared to treatment by hysterectomy in terms of quality of life at 26, 52 and 104 weeks after treatment (measured by WHOQOL-Bref and SF-12)

Secondary outcome

The two treatments will also be compared in terms of:
• Clinical outcomes (PBAC, NRS 0-100 scale, Facet 1:Pain and discomfort WHOQOL-100, Satisfaction with allocated treatment (likert-scale), patient preference)
• Recovery related outcomes (RI-10)
• Quality of life outcomes (HOQOL-Bref and SF-12)
• Cost outcomes (EQ-5D)
• Imaging outcomes (uterine size reduction, infarction rate, junctional zone reduction, concomitant fibroids)

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. 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.

Objective of the study:
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. 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).

Study design:
2015-2018: Non-blinded randomized controlled trial and cohort alongside the trial.
2018-2021: case-control cohort study

Study population:
Premenopausal women without the desire to conceive and who have symptomatic MRI confirmed pure adenomyosis or dominant adenomyosis in combination with fibroids. (If the deep fibroids are clearly less to the extent of adenomyosis in terms of volume we consider it dominant adenomyosis)

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

Primary study parameters/outcome of the study:
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.

Secundary study parameters/outcome of the study (if applicable):
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 objective

This study aims to evaluate the impact of UAE on Quality of life (QOL) in comparison to hysterectomy in adenomyosis patients.

Study design

Measurements: will be taken at baseline and 6, 12, 26, 52 and 104 weeks after therapy.

Intervention

Uterine artery embolization -> experimental treatment
Hysterectomy -> standard care

Contacts

Public
Arts-onderzoeker QUESTA-studie www.questa-studie.nl

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Eligibility criteria

Inclusion criteria

• Premenopausal women with MRI confirmed symptomatic adenomyosis or dominant adenomyosis in combination with fibroids.
• Premenopausal women with an indication for hysterectomy.
• No wish to conceive in the present or future
• Able to understand Dutch 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:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2015
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55436
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5471
NTR-old	NTR5615
CCMO	NL52652.029.15
OMON	NL-OMON55436

Study results