QUality of life after Embolization vs. hySTerectomy in Adenomyosis.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23586

Bron
Nationaal Trial Register

Verkorte titel
QUESTA trial: QUality of life after Embolization vs. hySTerectomy in Adenomyosis.

Aandoening

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)

Ondersteuning

Primaire sponsor: VU Medical Center
Overige ondersteuning: 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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Uterine artery embolization -> experimental treatment

Hysterectomy -> standard care

Contactpersonen

Publiek

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

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Wetenschappelijk

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

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-11-2015
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55436
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten