Operatieve of medicamenteuze behandeling van vrouwen met een endometrioom.

No registrations found.

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

Summary

ID

NL-OMON22624

Source
NTR

Brief title
SOMA-trial

Health condition

- Endometrioma/Endometrioom
- Medical treatment vs Surgical treatment/ Medicamenteuze vs Chirurgische behandeling
- Pain/ Pijn
- Quality of Life/ Kwaliteit van leven
- Affective symptoms/ Affectieve klachten
- Cost efficacy/ Kosteneffectiviteit
- Ovarian reserve/ Ovariële reserve

Sponsors and support

Primary sponsor: Maxima Medical Center.
Source(s) of monetary or material Support: ZonMw.

Intervention

Outcome measures

Primary outcome

The primary outcome is: effectiveness of surgical treatment compared to treatment with medication, defined as:

- Successful pain reduction (- 30% reduction of pain on visual analog scale [VAS]) after 6 months;

Secondary outcome

The secondary outcomes include:

- Succesful pain reduction after 12 and 18 months;

- Quality of life: measured by the EuroQoL-5D, SF36v and EHP30 questionnaires and this will be used to calculate QALY and productivity loss;

- Affective symptoms; measured by the GAD-7 and PHQ-9 questionnaires.
- Costs effectiveness: health care costs, patients and family costs and productivity costs measured from a societal perspective using internet questionnaires based on the iMCQ and iPCQ.
- Recurrence rate: recurrence of either pain symptoms (measured on the VAS) and the endometrioma itself (measured with ultrasound)

- Need of adjuvant medication (analgesics and/or hormones) after surgery, measured with a medication journal;

- Ovarian reserve: measured by blood test (AMH levels) and ultrasound (AFC).

- Adjuvant surgery: rate of adjuvant surgery 6 months after treatment with medication for endometrioma.

Study description

Background summary

This multicenter randomized controlled trial will compare the effectiveness (in terms of successful pain relief and quality of life) and cost-effectiveness of surgical treatment with medical treatment of women with an endometrioma and pain symptoms in order to justify de-implementation of the least cost-effective treatment strategy and further implementation of the most cost-effective strategy. The secondary objectives are to obtain more insight in the recurrence rate of endometrioma after surgical treatment and the ovarian reserve

compared to medical treatment.

Study objective

This study aims to reject the null-hypothesis that medical treatment and surgical treatment are equally (cost-)effective. This study aims to test the alternative hypothesis that surgical treatment is the most effective regarding pain relief, improving quality of life and more cost-effectiveness when compared to medical treatment. Potential recurrence of symptoms and decreased ovarian reserve after surgery have to be taken into account to test the hypothesis.

Study design

Follow-up will take place 6 weeks, 6 months, 12 months and 18 months after (start of the) treatment.

Intervention

Surgical treatment.

Contacts

Public
MUMC
Esther van Barneveld

-
Scientific
MUMC
Esther van Barneveld

-

Eligibility criteria

Inclusion criteria

1. Premenopausal woman aged ≥ 18 years;

2. Patients who report one of the endometriosis related pain symptoms dysmenorrhoea, pelvic pain or dyspareunia;

3. Endometrioma ≥ 3 cm (by ultrasound or MRI).

Exclusion criteria

1. Women with signs of deep endometriosis (by physical examination, ultrasound or MRI);

2. Not able or willing to provide written informed consent;

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	184
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-12-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56253
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7447
NTR-old	NTR7689
CCMO	NL67922.015.18
OMON	NL-OMON56253

Study results