Surgery or Medication for women with Endometrioma.

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What is the effectiveness and cost-effectiveness of surgical treatment of women suffering from pain due to an endometrioma when compared to treatment with medication?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational invasive

Summary

ID

NL-OMON56253

Source
ToetsingOnline

Brief title
SOMA-trial.

Condition

- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
endometrioma, Endometriosis, endometriosiscyst

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cost efficacy, Endometrioma, Pain reduction and quality of life, Surgical vs treatment with medication

Outcome measures

Primary outcome

Successful pain reduction (- 30% reduction of pain on numeric rating scale

[NRS]) after 6 months.

Secondary outcome

o Successful pain reduction after 12 and 18 months measured by the numeric

rating scale as described above;

o Quality of life: measured by the EuroQoL-5D-5L and EHP30 questionnaires.

This will be used to calculate QALY and productivity loss;

o Affective symptoms: measured by the GAD-7 and PHQ-9 questionnaires.

o 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;

o Recurrence rate: recurrence of either pain symptoms (measured on the NRS

as described above) and the endometrioma itself (measured

with ultrasound);

o Need of adjuvant medication (analgesics and/or hormones) after surgery. This

information will be provided from the patients medical file by a local

investigator or research nurse;

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

AMH will only be measured in the randomised controlled trial;

o Adjuvant surgery: rate of adjuvant surgery after treatment with medication for endometrioma. Adjuvant surgery will be offered in case of insufficient pain relief 6 months after treatment with medication;

o Budget impact: calculated at the end of the trial by comparing total costs from the group treated with medication and the group treated by surgery.

o Best Worst Score: BWS scores are calculated using the following formula: **number of times attribute selected as best** - ** number of times attribute selected as worst**/number of times attribute appeared. BWS scores range from -1.0 to 1.0, where -1.0 reflects the worst (attribute selected as worst in every question) and 1.0 reflects the best (attribute selected as best in every question), a score of 0 means that the attribute was selected as best and as worst an equal number of times.

Study description

Background summary

Two therapeutic strategies are available for the treatment of endometrioma, including medication (analgesia and/or hormones) and surgical treatment. Evidence suggests that both treatment with medication and surgery are effective in reducing pain. However, there are no randomized studies that compared surgery to medication. This forces women with endometrioma and physicians to take decisions in uncertainty about the benefits, risks and cost-effectiveness of surgery in direct comparison with treatment with medication.

Study objective

What is the effectiveness and cost-effectiveness of surgical treatment of women suffering from pain due to an endometrioma when compared to treatment with medication?

Study design

Multicenter prospective cohort trial. In the beginning this was a randomized controlled trial with cost-effectiveness analysis and preference study. Non-randomized women, who had a preference for one of the treatments, would be treated according to their preference and asked for inclusion in a prospective cohort.

Intervention

Surgical treatment compared to treatment with medication (hormone therapy/analgesics) for endometriosis.

Study burden and risks

Both medical treatment and surgical treatment are part of the standard care for endometriomas. Therefore no additional risks are expected. Patients who participate in this study might undergo surgery earlier than they would during the current standard care.

Possible disadvantage of surgery:
One of the risks of surgery is recurrence of the cyst, causing relapse of symptoms. Furthermore, some studies showed that healthy ovarian tissue is accidentally removed during surgery which may cause a loss of ovarian reserve. There is a small risk that the whole ovary has to be removed. As for every abdominal surgery, there is always a small risk of infection, bleeding and damage to intestines or urinary tract.

Possible disadvantage of treatment with medicines:
Treatment with medicines can cause side effects. The severity depends on the individual. The effect of medical treatment may be temporarily and women may experience insufficient pain relief or exacerbations of pain symptoms. Due to these disadvantages, surgery may still be necessary.

Most study visits will be combined with regular care visits and activities in order to reduce the burden of participation in this study. In regular care, patients treated with medication will have follow-up four times a year. Therefore, patients receiving treatment with medication during this study, will have no extra study visits. However patients treated by surgery in regular care only have follow-up at 6 weeks after treatment. Therefore patients treated with surgery in this study will get three extra study visits (at 6, 12 and 18 months).

• T0: Start of study
o After counselling and informed consent baseline characteristics will be measured (regular care, no additional visit).
o Regular care activities: defining the level op pain (on numeric rating scale, NRS), ultrasound including antral follicle count (AFC).

o Additional study activities: Quality of life and affective symptom questionnaires (EQ5D-5L, EHP30, GAD-7, PHQ-9), blood collection for anti-mullerian hormone(AMH).

• T1: 6 weeks follow-up:
o Regular care activities: NRS
o Additional study activities: Quality of life and affective symptom questionnaires.

• T2: 6 months follow-up
o NRS
o ultrasound, AFC
o AMH
o Quality of life, affective symptom and cost questionnaires.

In case of insufficient pain relief for patients in the medication group, adjuvant surgical treatment is offered.

• T3: 12 months follow-up:
o NRS
o ultrasound, AFC
o AMH
o Quality of life, affective symptom and cost questionnaires.

• T4: 18 months follow up:
o NRS
o ultrasound, AFC
o AMH
o Quality of life, affective symptom and cost questionnaires.

AMH is not measured in the Cohort-study.

Preference study:
o Filling in questionnaires: 45 minutes

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Premenopausal woman aged >= 18 years;
- Pain symptoms (dysmenorrhoea, pelvic pain or dyspareunia);
- Endometrioma >= 3 cm (confirmed by ultrasound or MRI).

Exclusion criteria

- Women with signs of deep endometriosis (by physical examination, ultrasound or MRI);
- Women who are not able or willing to provide written informed consent;

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-05-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-04-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-07-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-09-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	27-11-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-03-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-07-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-09-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-09-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	07-11-2023
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

ID: 22624
Source: NTR
Title:

In other registers

Register	ID
Other	7689
CCMO	NL67922.015.18
OMON	NL-OMON22624