A randomised controlled trial comparing endometrial ablation plus levonorgestrel releasing intrauterine system versus endometrial ablation alone in women with heavy menstrual bleeding (MIRA 2 trial).

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To determine whether the introduction of a levonorgestrel-releasing intrauterine system (LNG-IUS) directly after endometrial ablation (EA) alleviates pain and heavy menstrual bleeding and reduces the need for subsequent hysterectomy compared with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON54839

Source
ToetsingOnline

Brief title
MIRA 2 trial

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
dysmenorrhoea, pelvic pain

Research involving

Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Werkgroep leading the change

Intervention

Keyword: Dysmenorrhea., Endometrial ablation, Hysterectomy rate, Levonorgestrel-releasing intrauterine system

Outcome measures

Primary outcome

Primary: hysterectomy rate after 2 years of follow-up.

Secondary outcome

Patient satisfaction, PBAC-score, quality of life, cyclisch and non-cyclic

pelvic pain, side-effects, re-interventions, complications and

cost-effectiveness.

Study description

Background summary

Heavy menstrual bleeding (HMB) is a frequent problem affecting 1 in 4 women between 30 and 50 years. Endometrial ablation (EA) is a widely used procedure to treat HMB. However, 12-25% of women are dissatisfied after EA because of persisting abnormal uterine bleeding (AUB) and/or dysmenorrhea and most of these symptomatic women ultimately undergo a hysterectomy.

Adding a levonorgestrel releasing intrauterine system (LNG-IUS) inactivates the residual or regenerative endometrial tissue. This will reduce the pre-existing cyclical pelvic *period* pain and minimise or eradicate iatrogenic pelvic pain induced by intrauterine adhesion formation associated with endometrial ablative treatment. Although, adding a LNG-IUS is not usual care for heavy menstrual bleeding treatment.
We hypothesize that the combination of endometrial ablation and LNG-IUS is superior to endometrial ablation alone in terms of substantially reducing

subsequent rates of hysterectomy and alleviating pain and heavy menstrual bleeding.

Study objective

To determine whether the introduction of a levonorgestrel-releasing intrauterine system (LNG-IUS) directly after endometrial ablation (EA) alleviates pain and heavy menstrual bleeding and reduces the need for subsequent hysterectomy compared with endometrial ablation alone.

Study design

Multicentre randomized controlled trial.

Intervention

Endometrial ablation and LNG-IUS combined, control group is standard care with only an endometrial ablation.

Study burden and risks

This study investigates a combined treatment. However, whilst EA and LNG-IUS both are widely implemented as individual treatments, a combination of the two is seldom used for heavy menstrual bleeding. Perforation of the uterus is a small risk during or after insertion of a LNG-IUS. In a cohort study of Heineman et al. (n = 61.448), 1.4 uterine perforations were reported per 1000 patients who received a LNG-IUS. Patients will fill in 5 questionnaires in a period of 24 months. This will not impose extra risk on participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Women suffering from heavy menstrual bleeding, who opt for treatment with EA, irrespective of the existence of fibroids, polyps or adenomyosis.

Exclusion criteria

- Women who don*t speak Dutch or English to a standard that they can fully understand the study and complete the trial questionnaires.
- Women with a (future) childwish
- Women with a suspicion on endometrial cancer.
- Women with contra-indications for levonorgestrel IUD.
- Women with an already performed Endometrial Ablation.
- Women over 60 years old.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2019
Enrollment:	718
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	22-10-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-11-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	22-04-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-10-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-10-2020

Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-11-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-04-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-05-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-12-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-12-2023
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: 25628
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69895.015.19
Other	NL7817
OMON	NL-OMON25628