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

No registrations found.

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

Summary

ID

NL-OMON25628

Source
Nationaal Trial Register

Brief title
MIRA2

Health condition

Heavy menstrual bleeding
Dysmenorroea

Sponsors and support

Primary sponsor: Máxima Medical Centre
Source(s) of monetary or material Support: Leading the Change project

Intervention

Outcome measures

Primary outcome

Hysterectomy rate after 2 years of follow-up.

Secondary outcome

Patient satisfaction, PBAC-score, quality of life, cyclic and non-cyclic pelvic pain, re-interventions, complications, side-effects and cost-effectiveness.

Study description

Background summary

Rationale
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.

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

Study design
Multicentre randomized controlled trial.

Study population
Women suffering from heavy menstrual bleeding without contraindications for use of the LNG-IUS who opt for treatment with EA.

Intervention
Endometrial ablation and LNG-IUS combined.

Usual Care / comparison
Endometrial ablation alone

Main study parameters / endpoints
Primary: hysterectomy rate after 2 years of follow-up.
Secondary: patient satisfaction, PBAC-score, quality of life, cyclic and non-cyclic pelvic pain, re-interventions, complications, side-effects and cost-effectiveness.

Study objective

The hypothesis is that the combination of endometrial ablation and LNG-IUS is superior to endometrial ablation alone in terms of substantially reducing subsequent rates of hysterectomy within two year after treatment with 7%.

Study design

At baseline, after 6, 12, 18 en 24 months

Intervention

Endometrial ablation and LNG-IUS combined.

Contacts

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Eligibility criteria

Inclusion criteria

Women suffering from heavy menstrual bleeding, who do not wish or benefit from another treatment for heavy menstrual bleeding (medication or LNG-IUS) and opt for treatment with

EA, irrespective of the existence of fibroids, polyps or adenomyosis. Earlier use of LNG-IUS is no exclusion.

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 who might want to get pregnant in the future will not be included since an endometrium ablation interferes with future pregnancies.
• Suspicion on endometrial cancer.
• Contra-indications for levonorgestrel IUD.
• Already performed Eandometrial Ablation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2019
Enrollment:	718
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54839
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7817
CCMO	NL69895.015.19
OMON	NL-OMON54839

Study results