

# RCT comparing the levonorgestrel releasing intrauterine system (Mirena) versus endometrial ablation in women suffering from menorrhagia

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We plan to compare the costs and effects of both methods.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON41545

### Source

ToetsingOnline

### Brief title

MIRA

### Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Menstrual cycle and uterine bleeding disorders

### Synonym

Heavy menstrual bleeding, Menorrhagia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Ablatie, menorrhagia, Mirena

## Outcome measures

### Primary outcome

Primary outcome is the mean blood loss at 24 months of follow-up, measured with a PBAC-score.

### Secondary outcome

Secondary outcomes are patient satisfaction, complications, number of re-interventions, menstrual bleeding pattern, including rates of amenorrhea, proportion of women with a PBAC-score <75, quality of life, sexual function, presence of lower levels of coagulation levels, sick leave and costs.

## Study description

### Background summary

A levonorgestrel releasing intrauterine system (LNG-IUS) and endometrial ablation are two frequently used methods for the treatment of menorrhagia, of which the first can be applied by a general practitioner or a gynaecologist, whereas the second is exclusively applied by a gynaecologist.

### Study objective

We plan to compare the costs and effects of both methods.

### Study design

Randomised controlled trial with a cost-effectiveness analysis and analysis of coagulation factors alongside it.

## Intervention

We will assess cost-effectiveness of two methods that are frequently used in daily practice: a strategy starting with a levonorgestrel releasing intrauterine system versus a strategy starting with endometrial ablation for the treatment of menorrhagia.

## Study burden and risks

As we compare to current treatment strategies, participation in this trial will not impose risk on the patients. Participants will be asked to fill out questionnaire at five moments; it will take them about 15 minutes each time to fill these out. Furthermore, we will take 12ml of blood at baseline from patients who give informed consent.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

Women suffering from menorrhagia, with a Pictorial Blood Assessment Chart (PBAC) exceeding 150 points

## Exclusion criteria

- \*the desire to have (more) children
- \*Women with an abnormal uterine cavity (myomas, polyps) determined by a transVaginalUltrasound (TVU)
- \* Women with large intramural myoma determined by a TVU
- \* Women younger than 34 years
- \* Sound length more than 10 cm measured at TVU
- \* Uterine size exceeding 10 weeks of gestation by bimanual manipulation

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-04-2012
Enrollment:	266
Type:	Actual

## Ethics review

Approved WMO	
Date:	08-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	27-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	23-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	23-04-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL38243.018.11