Randomised trial in women with heavy menstrual bleeding comparing Mirena IUD versus endomterial ablation.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19998

Source
Nationaal Trial Register

Brief title
MIRA

Health condition

Menorrhagia is defined as cyclic heavy menstrual bleeding (>80 ml) over several consecutive cycles. Menorrhagia is inconvenient, and it induces menstrual pain, anaemia, tiredness and sexual dysfunction, thus affecting quality of life. It is also associated with an increased medical consultation and menstruation-related sick leave. Various drug and hormonal therapies are applied and a substantial part of women suffering from menorrhagia receives a hysterectomy in the end, with an associated risk of complications and recovery associated sick leave. In many cases a clear cause for menorrhagia cannot be found.

key words: menorrhagia, cyclic heavy bleeding

key words (Dutch): menorhagie, hevig menstrueel bloedverlies

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

20-05-2013: The primary outcome will be blood loss at 24 months after randomization, measured with the PBAC-score.

Secondary outcome

Secondary measures of effectiveness will be the type and number of re-interventions after each treatment after 24 months, the rates of amenorrhea after the treatment at 6, 12 and 24 months and the pictorial chart scores at 6, 12 and 24 months and the quality of life scores as obtained from the SF 36 questionnaires.
20-05-2013: Measurement of VWF and Factor XI to investigate the prevalence of coagulation disorders and if lower levels of coagulation factors influence the effectiveness of the treatment. Separate informed consent will be asked for taking and analyzing blood from participating patients.

Study description

Background summary

OBJECTIVE:

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

DESIGN:

Randomised controlled trial with a cost-effectiveness analysis alongside it. Non-randomised patients, who have a preference for one of the treatments, will also be followed and included in the analysis.

PATIENTS:

Women without child wish suffering from menorrhagia, in whom medical treatment has failed, or was contraindicated or unacceptable to the patient. Before study entry, the menorrhagia will be quantified by a pictorial blood assessment chart (PBAC).

INTERVENTIONS:

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

OUTCOME MEASURE:

Primary outcome is the number of months that women are satisfied with the treatment result during a follow-up period of 24 months. Secondary outcomes are complications, number of re-interventions, menstrual bleeding pattern, including rates of amenorrhea, mean blood loss per month (PBAC score), quality of life, sexual function, sick leave and costs.

SAMPLE SIZE:

Using an equivalence assumption with a 90% success rate for both groups and an acceptable difference in success rate of at maximum 15%, we need to include 314 women (157 women per arm) (alpha error 5% Beta error 20%).

ECONOMIC EVALUATION:

The economic evaluation will be conducted from a societal perspective. Cost-effectiveness and cost-utility analyses will be performed and uncertainty presented on cost-effectiveness planes. Acceptability curves will be presented as well and sensitivity analyses performed on the most important cost drivers.

TIME PHRAME:

From January 2012 till May 2016. The initiation phase will take four months. Recruitment and inclusion phase in 18 months with a follow-up of 24 months. Analysis will take place from end 2015 to May 2016.

Study objective

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

Study design

Participating women will fill in questionnaires at baseline, 1 week, 3 months, 6, 12 months and 24 months. Questionnaires will contain:

1. Specific questions about the menstruation using the Shaw menstruation questionnaire (see attachment). Women will be asked to describe their menstruations over the period since the previous questionnaire;

2. Pictorial chart according to Higham to quantify menstrual bleeding (see attachment);

3. SF 36 quality of life questionnaire to get informed of general health;

4. Questionnaire of direct and indirect costs (200 patients);

5. Preference list of the balance between the effectiveness of two therapeutic options, the chance of complications and side effects and the investigation itself (LNG-IUS and endometrial ablation).

Intervention

After randomisation, women allocated to LNG-IUS will get a device inserted by a general practitioner or a gynaecologist, whereas women allocated to endometrial ablation will be scheduled for endometrial ablation under local or under general anaesthesia. Only general practitioners and gynaecologists who are used to perform these treatment options in daily practice, will participate in the study.

Levonorgestrel releasing intrauterine system (LNG-IUS) :

The introduction of an IUS is an outpatient procedure normally without anaesthesia. Most general practitioners can place the LNG-IUS by themselves, although there is a difference per region. In this study a general practitioner or a gynaecologist can place the LNG-IUS after referral. The doctor, who referred the patient to the research nurse will place the LNG-IUS unless he or she does not have the expertise.

Endometrial ablation:

Women allocated to ablation will be scheduled for a visit to the gynaecologist. The endometrial ablation will be performed in specialised centres using second-generation devices. Depending on the local situation in each centre, ablation will be performed in the outpatient theatre under local anaesthetics or conscious sedation or in the operation room under general or spinal anaesthesia. Each centre will use the device that is routinely used in their setting (mostly the Novasure device or the Thermachoice device.)

In both arms, women can get additional treatments if the result of the primary therapy is insufficient after 6 months. For example, when the result of an LNG-IUS is unsatisfactory, the woman can be treated with ablation or even hysterectomy, Similarly, women not satisfied with the result of an ablation can opt for a hysterectomy. When such re-interventions occur, women will stay in the study, and asked to continue the completion of the questionnaires.

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Eligibility criteria

Inclusion criteria

We will study women suffering from menorrhagia. Menorrhagia will be defined as a report of

cyclic heavy menstrual bleeding confirmed by a Pictorial Blood Assessment Chart (PBAC) exceeding 150 points. These women can either have had medical treatment without success for menorrhagia or decided that such treatment is no option for them.

Exclusion criteria

1. Women with further child wish. Women with potential child wish will not be included since an endometrium ablation interferes with future pregnancies;

2. Women with an abnormal uterine cavity (myomas, polyps) determined by a TVU;

3. Women with large intramural myoma determined by a TVU;

4. Women younger then 34 years;

5. Abnormal cervical cytology;

6. Sound length more then 10 cm measured at TVU;

7. Uterine size exceeding 10 weeks of gestation by bimanual manipulation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	266
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL2842
NTR-old	NTR2984
Other	ZonMw : 80-82310-97-12040
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A