RCT comparing insertion of levonorgestrel releasing intrauterine system (Mirena) during the menstruation compared with random insertion beyond menstruations in patient-perceived pain.

Published: 19-09-2013
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON40263

Source
ToetsingOnline

Brief title
Timing Insertion MirEna trial (TIME trial)

Condition

- Menstrual cycle and uterine bleeding disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
intrauterine contraceptive, LNG-IUS

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: het valt onder reguliere zorg;dus er is geen extra geldstroom noodzakelijk

Intervention

Keyword: insertion, menstruation, Mirena, pain

Outcome measures

Primary outcome

Primary outcome is the patient-perceived pain during insertion of LNG-IUS using

the VAS scale.

Secondary outcome

Secondary outcomes are ease of insertion and short-term outcomes, i.e.

satisfaction, removal, expulsion, pregnancy rates, and bleeding pattern during

a follow-up of three months.

Study description

Background summary

A levonorgestrel releasing intrauterine system (LNG-IUS) is a common contraceptive. LNG-IUS induces endometrial suppression and reduces menstrual bleeding which makes this intrauterine system a very popular form of contraception. LNG-IUS is also used in treatment of menorrhagia, endometriosis and in protection of endometrium in women receiving estrogen replacement therapy. Insertion is performed by a general practitioner or a gynaecologist mostly during menstruation. Insertion during menstruation prevents unintentional insertion during (early) pregnancy. In theory insertion during menstruation is less painful because of a dilated cervical ostium during menstruation. Also in theory, starting release of progestogens could be better during the breakdown of the endometrium in order to prevent prolonged bleedings. For copper-IUDs it is proven there is no difference in timing during menstrual cycle regarding patient-perceived pain.

Study objective

In this randomized study, timing during (day 1-7 of the menstruation cycle WITH vaginal blood loss) or beyond menstruation (in menstruation cycle day 8 and further WITHOUT vaginal blood loss) will be compared regarding differences in patient-perceived pain.
The secondary outcome will be easiness of insertion by the Physician Assistant, scaled as easy or difficult (scored as difficult whenever advanced tools were necessary to use for a successful insertion, for example cervical dilatation or hysteroscopy) and short-term outcomes, i.e. patient satisfaction with LNG- IUS, removal rate, expulsion rate and pregnancy rate, and bleeding pattern during a follow-up of three months. After three months we will perform a 2D/3D ultrasound investigate if malposition is related tot the secundary outcomes.

Study design

Randomized controlled trial according to an intention to treat analysis.

Intervention

insertion of LNG-IUS beyond menstruation.

Study burden and risks

As this study compares one common treatment with two different regimens, it will not impose extra risk on the participants. Participants fill out questionnaires at three different occasions and a pictorial blood assessment chart (PBAC) daily within the three months following.
After three months we will perform a 2D/3D ultrasound investigate if malposition is related tot the secundary outcomes. The time to make the two ultrasounds will take approximately 5 minutes. In addition, it will take extra time for the patient to travel to the hospital, which depends on the place of residence.

Contacts

Public
Maxima Medisch Centrum

De Run 4600
Veldhoven 5500MB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5500MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women who menstruate with a wish for LNG-IUS

Exclusion criteria

* Women with an abnormal uterine cavity (myomas, polyps) determined by a TransVaginalUltrasound (TVU)
* Women with a failed insertion in a previous attempt, or with a LNG-IUS in situ and wish for change
* Women younger than 18 years
* Peri- or postmenopausal women
* Women with a positive pregnancy test or who had unprotected intercourse since their menses
* Amenorrhea after pregnancy

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:	Recruitment stopped
Start date (anticipated):	19-05-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	19-09-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-02-2014
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: 23626
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45003.015.13
OMON	NL-OMON23626