# RCT: LNG-IUS insertion during menstruation compared with random insertion beyond menstruations in patient-perceived pain.

No registrations found.

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

## Summary

### ID

NL-OMON23626

**Source**
Nationaal Trial Register

**Brief title**
TIME-trial

**Health condition**

anticonceptie/contraception
Mirena/LNG-IUS
insertion
pain

### Sponsors and support

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## Intervention

## Outcome measures

### Primary outcome

Patient-perceived pain during insertion of LNG-IUS using the Visual Analogue Scale (VAS)

### Secondary outcome

The secondary outcome will be easiness of insertion by the health care provider, 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 (scaled using the Likert scale ), removal rate, expulsion rate and pregnancy rate, and bleeding pattern during a follow-up of three months. After 3 months a 2D and 3D ultrasound will be made to check for expulsion and pregnancy rates.

# Study description

### Background summary

SUMMARY

Rationale/ Objective: 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. In this randomized study, timing during or beyond menstruation will be compared regarding differences in patient-pain perception and easiness of insertion as percepted by the doctor.

Study design: Randomized controlled trial according to an intention to treat analysis.

Study population: Women who are planned for an insertion of LNG-IUS as contraceptive or

treatment for menorrhagia. Before study entry, we will assess the risk for pregnancy. Intervention (if applicable): insertion of LNG-IUS during menstruation versus beyond menstruation.

Main study parameters/endpoints: Primary outcome is the patient-perceived pain during insertion of LNG-IUS using the VAS scale. 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 3 months we will perform a 2D and 3D ultrasound to check for expulsion and pregnancy rates.

Country of recruitment: The Netherlands

### Study objective

In theory insertion during menstruation is less painful because of a dilated cervical ostium during menstruation.

### Study design

- Directly after insertion (VAS scale)
- monthly until 3 months after insertion of LNG-IUS (using questionnaires for satisfaction using the Likert scale and Pictorial Blood Assessment charts (PBAC)
-after 3 months a 2D and 3D ultrasound will be made to check the lokalisation (check for expulsion/pregnancy, i.e. secondary outcomes)

### Intervention

insertion of LNG-IUS DURING (controlgroup) versus Beyond menstruation (interventiongroup). After insertion, which only takes about 5 minutes, patients are asked to give a VAS scale (0-100 mm) to describe the pain perceived DURING insertion

## Contacts

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# Eligibility criteria

## 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 either bij general practitioner or other Gyneacologist

• Women with a LNG-IUS in situ with request for reinsertion

• 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

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|---|---|
| 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): | 01-10-2013 |
| Enrollment: | 120 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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| Date: | 12-11-2013 |
| Application type: | First submission |

# Study registrations

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

ID: 40263
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL4015 |
| NTR-old | NTR4258 |
| CCMO | NL45003.015.13 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON40263 |

# Study results

**Summary results**
N/A