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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23626

Bron
Nationaal Trial Register

Verkorte titel
TIME-trial

Aandoening

anticonceptie/contraception
Mirena/LNG-IUS
insertion
pain

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

- 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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women who menstruate with a wish for LNG-IUS.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40263
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4015

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

Resultaten

Samenvatting resultaten
N/A