Treatment of irregular bleeding after insertion of the levonorgestrel-releasing Intrauterine System (LNG-IUS).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25280

Source
Nationaal Trial Register

Brief title
TreatMi

Health condition

irregular bleeding

Sponsors and support

Primary sponsor: Maxima Medical Centre
Source(s) of monetary or material Support: Maxima Medical Centre

Intervention

Outcome measures

Primary outcome

To evaluate the effect of oral estradiol (started at least 6 months after LNG-IUS insertion) on irregular bleeding

Secondary outcome

- The effect of oral estradiol use on the incidence of premature removal of the LNG-IUS.
- The occurrence of adverse events due to use of estradiol.

Study description

Background summary

The levonorgestrel-releasing Intrauterine System (LNG-IUS) releases levonorgestrel for five years. Irregular bleeding up to six months after insertion of the LNG-IUS often occurs. In some cases irregular bleeding continues after six months or returns over time. Up to 60% of women remove the LNG-IUS prematurely. An important reason for premature removal is occurrence of bleeding disturbances. The best treatment option for these bleeding disturbances is unknown.
To evaluate the effect of oral estradiol (started at least 6 months after LNG-IUS insertion) on irregular bleeding. Secondary objectives include the effect of estradiol use on incidence of premature removal of the LNG-IUS and the occurrence of adverse events due to use of estradiol.

Study objective

We hypothesize that the use of oral estradiol is effective in women with irregular bleeding with a LNG-IUS in situ for more than 6 months

Study design

baseline, 3 months and 12 months

Intervention

2mg estradiol for 6 weeks

Contacts

Public
Maxima Medisch Centrum
Tamara Oderkerk

0408888384
Scientific

Maxima Medisch Centrum
Tamara Oderkerk

0408888384

Eligibility criteria

Inclusion criteria

Women with a LNG-IUS in situ for more than six months, who visit the outpatient clinic with bleeding disturbances and opt for a treatment with oral estradiol

Exclusion criteria

- Women younger than 18 years
- Abnormal cervical cytology or malignancies of the uterus
- The presence of polyps, myomas on ultrasound
- A contra-indication for the use of estradiol (thrombosis or mamma carcinoma in patient history)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2017
Enrollment:	100

Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	23-07-2019
Application type:	First submission

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	NL8007
Other	METC MMC : N17.070

Study results