A multi-center, single-blinded, randomized, controlled, parallel-group study to evaluate the wearing comfort of two different placebo intrauterine systems FR01 and FR20 compared to a placebo T-frame intrauterine system for 3 cycles in healthy women aged 18-40 years

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To evaluate two different placebo intrauterine systems, pentagon-shaped placebo FR01 and traingle-shaped FR20 with different types of inserters, for wearing comfort, insertion/removal ease and pain compared to a placebo T-frame intrauterine system.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32633

Source
ToetsingOnline

Brief title
FR01 and FR20 IUS wearing study

Condition

- Other condition

Synonym
insertion/removal, wearing comfort

Health condition

draagcomfort en insertie/verwijdering van IUS

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Pharmaceutische industrie; Bayer Schering Pharma

Intervention

Keyword: intrauterine, wearing comfort

Outcome measures

Primary outcome

Pelvic pain during the IUS wearing period (wearing comfort) measured by 5-point

Likert scale (no pain/mild/moderate/severe/very severe pain).

Secondary outcome

- Need of painkillers due to pelvic pain during the wearing period

- Insertion/removal easiness evaluated by the physician

- Insertion/removal pain evaluated by the volunteer

- Need of pain relief during or after insertion

- Need of dilatation of the cervix

- Overall assessment of preference for insertion technique by the physician

- Frequency of expulsions

- Evaluation of menstrual bleedings

- Safety parameters: Basic lab (e.g. blood count, pregnancy test),- Pap smear,

Chlamydia/Gonorrhea, Ultrasound

Study description

Background summary

Aim of the study is to develop a levonorgestrel (LNG) releasing IUS for contraception for 3 years
with a simplified/easier insertion procedure, high wearing comfort for users, low risk of
perforation.
The concept consists of a new continuous frame with a LNG containing drug reservoir of the same core material as in
Mirena®, the LNG releasing IUS available on the global market since about 20 years. Placebo drug reservoirs,
round-shaped with concept FR01 and flat-shaped with concept FR20, will be used in the
planned first human study and will be compared with T-shaped IUS which is a smaller version of the earlier mentioned Mirena®.
Both concepts will be further developed for later phased clinical studies with an active drug
releasing reservoir. There is, therefore, no need to show superiority between the products at
this stage of the product development.

Study objective

To evaluate two different placebo intrauterine systems, pentagon-shaped placebo FR01 and traingle-shaped FR20 with different types of inserters, for wearing comfort, insertion/removal ease and pain compared to a placebo T-frame intrauterine system.

Study design

Randomized, multicenter, single blinded, controlled, parallel group study
No active drug substance
Treatment duration: 3 months
Study sites from 2-3 countries, 10 sites
Totally around 90, minimum 30/group

Intervention

The subjects will be randomized in three arms. In each arm one of the following IUS systems will be evaluated:

1. pentagon-shaped placebo FR01
2. traingle-shaped placebo FR20
3. placebo T-frame intrauterine system

Study burden and risks

Discomfort during insertion

Accidental pregnancy (the IUS have no contraceptive efficacy, therefore COC is prescribed).

Expulsion of the intrauterine system is possible.

Uterine perforation occurs in 1 out of 1000 insertions.

An IUS with no drug release may increase the amount of bleeding and frequency of menustrual bleeding/spotting

Pelvic infection is possible in this study. Such infection is mainly associated with behavioral factors such as multiplicity of sexual partners.

Other side effects might be lower abdominal pain, pelivic and back pain, inflammation of the genitials and cervicitis, which is an infection, in the opening of the womb.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy Female subject
Age 18-40 years (inclusive)
History of regular cyclic menstrual periods at baseline (cycle length 21 to 35 days)
Women using any COC for contraception with a monthly regimen before the study entry.
Confirmed uterine sound depth of 6 to 10 cm

Exclusion criteria

Pregnancy or lactation
Sterilized
Nulliparous
Congenital or acquired uterine anomaly
Vaginal or cesarean delivery within 8 weeks prior to insertion

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2010
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	intrauterine system
Registration:	No

Ethics review

Approved WMO Date:	08-01-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-02-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-02-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
CCMO	NL30606.040.09