Does Misoprostol facilitate insertion of an Intra Uterine Device (IUD), both copper-containing as well as levonorgestrel-releasing, among nulli- and multipara?

Published: 01-02-2007
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To investigate whether Misoprostol (compared to placebo) will diminish the amount of insertion failures. To investigate whether Misoprostol (compared to placebo) will diminish the amount of insertion related complications (eg. syncope, perforation...

Ethical review	Approved WMO
Status	Pending
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON30516

Source
ToetsingOnline

Brief title
Misoprostol before IUD-insertion

Condition

- Procedural related injuries and complications NEC

Synonym
IUD-insertion complications

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: researchfonds

Intervention

Keyword: insertion failure, insertion-related complications, IUD, Misoprostol

Outcome measures

Primary outcome

The amount of failed insertions

Secondary outcome

The amount of insertion related failures.

The subjectively experienced pain by the patient, recorded by VAS (Visual

analog Scale).

Study description

Background summary

It is known that insertion of IUD, especially with nullipara, sometimes fail or happen to be complicated (eg. by syncope, perforation of cervix or uterus or by creating a false passage) mostly due to severe cervical stenosis, immature cervix or significant anteflexion or retroflexion.
According to our hypothesis Misoprostol will cause softening and dilatation of the cervix which will diminish the amount of insertion failure and insertion related complications.

Study objective

To investigate whether Misoprostol (compared to placebo) will diminish the amount of insertion failures.
To investigate whether Misoprostol (compared to placebo) will diminish the amount of insertion related complications (eg. syncope, perforation of uterus or cervix).
To investigate whether Misoprostol (compared to placebo) will diminish the subjectively experienced pain by the patient, recorded by a Visual Analog Pain

Scale.

Study design

Randomised, double blind, placebo controlled study which will take place at the outpatient clinic of the Leiden University Medical Centre and a couple affiliated hospitals.

Intervention

133 patients will receive 400 µg Misoprostol and 133 deelnemers will receive placebo which they'll have to administer themselves vaginally three hours befoe IUD insertion. After administration they are required to lie down for half an hour.

Study burden and risks

A possible risk of participating in this trial, which might be a burden as well, is the risk of side-effects of Misoprostol. These are as followed:

Side-effects Misoprostol: (mostly dose-dependent) diarrhoea, abdominal pain, nausea, flatulence, vertigo, headache, constipation, vomiting, fever, dyspepsia and gynaecologic complaints like vaginal bleeding.

The patient will have to make one or two extra outpatient clinic visits because of her participation in this trial. This could be a time burden.

Other examinations, as eg. gynaecological examination and STD-screening, will not differ from examinations taken without participation in the trial.

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

All patients who want an IUD to be inserted can be included, regardless of the reason for IUD insertion, which can be a IUD as a contraceptive or a IUD as a therapeutic method for eg. hypermennoroeic complaints.
The IUD insertion can take place any moment during the menstrual cycle.

Exclusion criteria

- Pregnancy
- Lactation
- <6 weeks post-partum
- PID (Pelvic inflammatory disease)
- STD (sexually transmitted disease, like Chlamydia or Gonorrhea)
- Conus uteri
- Cervixcarcinoma
- Prostaglandin allergy
- Severely impaired liverfunction
- Cerebrovasculair disease
- Cavum uteri < 5cm of >9cm
- Undiagnosed abnormal uterine bleeding

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	270
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Cytotec®
Generic name:	Misoprostol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	01-02-2007
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2006-006897-60-NL
CCMO	NL15826.058.07