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

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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  $\mu$ g 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**

### **Public**

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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</li>
- 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