A multi-centre, randomized, double-blind trial studying the effect of misoprostol on the outcome of intra-uterine insemination.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29376

Source
NTR

Brief title
A multi-centre, randomized, double-blind trial studying the effect of misoprostol on the outcome of intra-uterine insemination.

Health condition

Intra-uterine insemination, misoprostol, pregnancy, prostaglandin, vaginal suppository.

Sponsors and support

Primary sponsor: Prof. Dr. M. Dhont, Vrouwenziekten, De Pintelaan 185, 9000 Gent, Belgium, Marc.Dhont@Ugent.be, 0032/9240.37.96.
Source(s) of monetary or material Support: Multi-centre study sponsored by VVOG (Vlaamse vereniging voor obstetrie en gynaecologie).

Intervention

Outcome measures

Primary outcome

Primary outcome is clinical pregnancy defined as the presence of a fetal sac with positive cardial activity.

Secondary outcome

Secondary endpoints are adverse reactions: uterine cramps and vaginal bleeding.

Study description

Background summary

Because seminal prostaglandins play a role in the natural fertilization process, it can be hypothesized that the vaginal supplementation of exogenous prostaglandins at the time of intra-uterine insemination might enhance the chances of conception. We therefore investigate the effect of misoprostol, a prostaglandin analogue, on the success rate of intra-uterine insemination.

Study objective

Pregnancy rate after insemination would be 50% higher after application of misoprostol.

Study design

N/A

Intervention

Before removing the speculum after IUI, a white study suppository is placed in het posterior vaginal fornix. Each suppository contains either placebo or 400 µg of misoprostol.

Contacts

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Eligibility criteria

Inclusion criteria

1. All women presenting for intra-uterine insemination;

2. Between the age of 20 and 36 years;

3. Bilateral tubal patency was proven;

4. Total motile fraction of the semen sample was more than 1 million after preparation;

5. Informed consent.

Exclusion criteria

1. History of previously failed intra-uterine insemination;

2. Severe comorbidity (endometriosis, fibroma);

3. Previous allergic reactions to misoprostol.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2003
Enrollment:	217
Type:	Actual

Ethics review

Positive opinion

Date:	16-04-2007
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	NL936
NTR-old	NTR961
Other	:
ISRCTN	ISRCTN76424181

Study results

Summary results

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