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

Public

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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

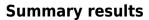
Register ID
NTR-new NL936

NTR-old NTR961

Other

ISRCTN ISRCTN76424181

Study results



Gynecol Obstet Invest. 2008 May 20;66(3):145-151. [Epub ahead of print]