

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

Submission date 30/05/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/05/2007	Overall study status Completed	☐ Protocol
Last Edited 19/10/2021	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NL936 (NTR961)

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University Hospital, De Pintelaan 185, 9000 Gent. Date of approval 17 May 2001. Project No. 2001/137.

Primary study design

Interventional

Study design

Randomised, multicentre, double blinded, placebo controlled, crossover trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pregnancy, prostaglandin, misoprostol, vaginal suppository, Intra-Uterine Insemination (IUI)

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

Clinical pregnancy defined as the presence of a intra-uterine fetal sac with positive cardial activity 5 weeks after insemination.

Key secondary outcome(s)

Adverse reactions: uterine cramps and vaginal bleeding until 24 hours after insemination.

Completion date

30/06/2005

Eligibility

Key inclusion criteria

1. All women presenting for Intra-Uterine Insemination (IUI)
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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. History of previously failed intra-uterine insemination
2. Severe comorbidity (endometriosis, fibroma)
3. Previous allergic reactions to misoprostol

Date of first enrolment

01/10/2003

Date of final enrolment

30/06/2005

Locations**Countries of recruitment**

Belgium

Netherlands

Study participating centre

Universitair Ziekenhuis Gent

Geent

Belgium

9000

Sponsor information

Organisation

University Hospital Ghent (Belgium)

ROR

<https://ror.org/00xmkg704>

Funder(s)

Funder type

Research organisation

Funder Name

Flemish Association for Obstetrics and Gynaecology (Vlaamse Vereniging voor Obstetrie en Gynaecologie) (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2008	19/10/2021	Yes	No