

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	<input type="checkbox"/> Prospectively registered
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/10/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr M. Dhont

Contact details

Universitair Ziekenhuis Gent
Vrouwenziekten
De Pintelaan 185
Gent
Belgium
9000
+32 (0)9 2403796
Marc.Dhont@Ugent.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2003

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

Age group

Adult

Sex

Female

Target number of participants

217

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)

Sponsor details
Department of Gynaecology
De Pintelaan 185
Gent
Belgium
B-9000

Sponsor type
Hospital/treatment centre

Website
<http://www.uzgent.be/EN/>

ROR
<https://ror.org/00xmkp704>

Funder(s)

Funder type
Research organisation

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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