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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

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