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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
30/05/2007

Recruitment status
No longer recruiting

Registration date
30/05/2007

Overall study status
Completed

Last Edited
19/10/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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.

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

Primary study design
Interventional

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/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

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