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Nitroglycerin for management of retained placenta: a multicentre trial

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/10/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/10/2008	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-001346-92

Protocol serial number
EudraCT number:

Study information

Scientific Title

Medical treatment with nitroglycerin for management of retained placenta: a multicentre trial

Study objectives
To study the effect of medical treatment with 1 mg of nitroglycerin administered sublingually on retained placenta, i.e. does placenta detach on the treatment?

Background:
Retained placenta occurs in 3% of all deliveries. The results from a pilot study indicate that medical treatment with a combination of oxytocin and the utero-relaxing agent nitroglycerin adminstered 1 mg sublingually seems to have an effect. The primary aim of this study is to investigate in a larger multicentre trial if the good results from the pilot study using nitroglycerin for management of retained placenta can be confirmed. Every woman who 30 minutes after vaginal delivery has a retained placenta and can be recruited to the study according to inclusion and exclusion criteria will be asked to participate in the study. The multicentre trial will be performed in the Swedish cities of Gothenburg, Trollhattan, Boras and Norrkoping.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Committee of Gothenburg, approved on the 5th May 2008 (ref: 107-08)

Primary study design
Interventional

Study design
Multicentre randomised placebo controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Retained placenta

Interventions
If placenta has not detached 30 minutes after delivery the patient will be given 10 IU oxytocin (Syntocinon®) intravenously. Five minutes later the doctor tries to expel the placenta by gentle traction of the umbilical cord. If the placenta doesn't detach the patient will be asked to participate in the study and will randomly be selected to either active treatment or placebo.

Of 120 patients included in the study 60 will randomly be selected to be administered two tablets of 0.5 mg glyceryl trinitrate (Nitromex®) sublingually, and 60 patients in the placebo group will be administered two tablets of 5 mg folic acid (Folacin®). The administration will occur approximately 45 minutes after the vaginal delivery and only once.

If placenta does not detach 5 minutes later the patient will be taken to the operative theatre for manual removal of the placenta in regional or general anaesthesia. The follow up of the outcomes will be performed up to 30 minutes after inclusion to the study, more specifically until the placenta is detached.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oxytocin (Syntocinon®), glyceryl trinitrate (Nitromex®), folic acid (Folacin®)

Primary outcome(s)
The numbered of detached placentas following sequential treatment with 10 IU oxytocin intravenously and 1 mg nitroglycerin sublingually compared to placebo group.

Key secondary outcome(s)
1. To measure blood loss on the treatment compared to placebo group, at 0 minutes, 5 minutes and 15 minutes. The amount of blood loss will be measured before and after detachment and the total blood loss until placental delivery will be measured.
2. To study possible side effects such as headache, palpitations, hot flushes, at 0 minutes, 5 minutes and 15 minutes
3. To study possible effects on blood pressure and pulse rate, at 0 minutes, 5 minutes and 15 minutes

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Healthy women with no medication, aged 18 - 45 years
2. Uncomplicated vaginal delivery
3. Term pregnancy (greater than 37 weeks)
4. Retained placenta 45 minutes after delivery
5. The woman wishes to participate in the study
6. No excessive vaginal bleeding (less than 500 ml)
7. Circulatory stability

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Excessive vaginal bleeding
2. Preterm labour
3. Daily medication
4. Placenta accreta/percreta
5. Known uterine abnormailty

Date of first enrolment
01/10/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Kvinnokliniken Ostra Hospital
Gothenburg
Sweden
41685

Sponsor information

Organisation
The Vastra Gotaland Regional Council (Vastra Gotalandsregionen) (Sweden)

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Research organisation

Funder Name
The Gothenburg Medical Society (Goteborgs Lakaresallskap) (Sweden) - Regional FoU resources

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration