

Nitroglycerin for management of retained placenta: a multicentre trial

Submission date 30/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/10/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 administered 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 Norrköping.

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)

Study design

Multicentre randomised placebo controlled trial

Primary study design

Interventional

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 abnormality

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