Misoprostol in the management of retained placenta, a safe alternative for manual removal? A randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20129

Source
NTR

Health condition

Retained placenta

Sponsors and support

Primary sponsor: Giel van Stralen
Source(s) of monetary or material Support: Self-financing

Intervention

Outcome measures

Primary outcome

1. Number of spontaneous delivered placentas;
2. Number of manual removals and amount of blood loss.

Secondary outcome

1. Interval between delivery of the baby and administration of misoprostol;
2. Interval between administration of misoprostol and delivery of the placenta;
3. Placenta captiva.

Study description

Background summary

Objective
To assess the effectiveness of misoprostol in the management of retained placenta. Will 800 micrograms of misoprostol orally reduce the need for manual removal under general anaesthesia and prove to be a safe alternative?
Method
All women with retained placenta after vaginal birth will be included in our study. Misoprostol 800 mcg or placebo will be administered. If a final attempt to deliver the placenta by controlled cord traction after 45 minutes fails, manual removal of the placenta will be performed. Side effects will be registered.
Sample size
Considering the results of our pilotstudy and historical data we want to include 100 women.
Outcome
Primary: number of spontaneous delivered placentas, number of manual removals and amount of blood loss. Secondary: interval between delivery of the baby and administration of misoprostol, interval between administration of misoprostol and delivery of the placenta, placenta captiva.

Study objective

The use of 800 mcg of misoprostol prevents manual removal of the retained placenta in 80% of cases.

Intervention

In case of retained placenta: administration of either 800 mcg of misoprostol or placebo 60 minutes after birth of the baby, in absence of postpartum haemorrhage

Contacts

Public
Leiden University Medical Center (LUMC), Department of Gynaecology

Giel Stralen, van
Leiden
The Netherlands
Scientific
Leiden University Medical Center (LUMC), Department of Gynaecology
Giel Stralen, van
Leiden
The Netherlands

Eligibility criteria

Inclusion criteria

1. All women with at least 25 completed pregnancy weeks and retained placenta;
2. At least 18 years of age;
3. Master the Dutch language in word and script.

Exclusion criteria

1. Excessive blood loss (>1000 ml) within 60 minutes after the delivery of the newborn;
2. Allergy for misoprostol or one of its components.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	100

Type:	Anticipated

Ethics review

Positive opinion Date:	25-06-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL975
NTR-old	NTR1002
Other	:
ISRCTN	ISRCTN45330307

Study results