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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/08/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/08/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
07/10/2021	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/08/2007, local medical ethics committee (Commissie Medische Ethiek), ref: P07-011

Study design

Multicentre randomized double-blinded placebo-controlled parallel-group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Retained placenta

Interventions

All women with retained placenta after vaginal birth will be included in our study. In the case of a retained placenta, administration of either 800 mcg of misoprostol or placebo 60 minutes after birth of the baby will be performed, in absence of postpartum haemorrhage. 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.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

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

Key secondary outcome(s))

- 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

Completion date

01/08/2009

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Total final enrolment

99

Key exclusion criteria

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

Date of first enrolment

01/08/2007

Date of final enrolment

01/08/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden Netherlands 2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

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		21/01/2013	07/10/2021	Yes	No