

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

Submission date 23/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/08/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/10/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Giel van Stralen

Contact details

Leiden University Medical Centre (LUMC)

Department of Gynaecology

Leiden

Netherlands

2300 RC

-

G.van_Stralen@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/08/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

100

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)

Sponsor details

Department of Gynaecology

P.O. Box 9600

Leiden

Netherlands

2300 RC

Sponsor type

Hospital/treatment centre

Website

http://www.lumc.nl/english/start_english.html#http://http://www.lumc.nl/english/start_english.html

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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