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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

Registration date
23/08/2007

Overall study status
Completed

Last Edited
07/10/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Leiden University Medical Centre (LUMC) (The Netherlands)

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