

Misoprostol for preventing postpartum haemorrhage

Submission date 24/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/03/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4.3

Study information

Scientific Title

Optimising the dose of Misoprostol for the prevention of postpartum haemorrhage: a randomised trial

Study objectives

Lower doses of misoprostol produce as strong postpartum uterine contractions as 10 IU of intramuscular (IM) oxytocin

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Liverpool Committee on Research Ethics approved on the 26th of June 2009 (ref: RETH000237)

Study design

Multicentre randomised controlled parallel group dosage trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Postpartum haemorrhage

Interventions

Treatment groups: 200 mcg or 400 mcg or 600 mcg sublingual misoprostol given once immediately post partum.

Control group: 10 IU IM oxytocin.

Observation of intrauterine pressure and vital sign for 120 minutes.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Montevideo units (MVU) (contractions over 10 minutes) for intrauterine pressure values over the first 15 minutes after placental delivery (Baby delivery)

Secondary outcome measures

1. MVU at 30, 60, 90 and 120 minutes
2. Pulse, blood pressure, and temperature at 30, 60, 90 and 120 minutes
3. Blood loss, measured in the 120 minutes after delivery

Overall study start date

16/08/2009

Completion date

15/09/2010

Eligibility

Key inclusion criteria

1. Women who have had spontaneous vaginal delivery
2. Women with gestational age >34 weeks
3. Women who give an informed written consent
4. Aged ≥ 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

60

Key exclusion criteria

1. Women with history of Postpartum Haemorrhage (PPH)
2. Women with history of Antepartum Haemorrhage (APH)
3. Women with previous caesarean section
4. Women with 5 or more previous deliveries at over 28 weeks
5. Women who have Premature Rupture of Membranes (PROM)
6. Women with anaemia (Hb <10g/dl)
7. Women who have given birth to a baby of birth weight > 4.0 Kgs
8. Women who have induced or augmented labour with any uterotonic drugs
9. Women with multiple pregnancies

10. Women with polyhydramnios
11. Women with pre eclampsia
12. Women with infection
13. Women who do not give a written consent

Date of first enrolment

16/08/2009

Date of final enrolment

15/09/2010

Locations

Countries of recruitment

England

Libya

United Kingdom

Study participating centre

School of Reproductive and Developmental Medicine

Liverpool

United Kingdom

L8 7SS

Sponsor information

Organisation

University of Liverpool (UK)

Sponsor details

General Research Enquiries

Research Support Office

The Foresight Building

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Sponsor type

University/education

Website

<http://www.liv.ac.uk/>

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

University/education

Funder Name

The University of Liverpool (UK)

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	results	01/03/2011		Yes	No