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Misoprostol for preventing postpartum haemorrhage

Submission date 24/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/05/2010	**Overall study status** Completed	
Last Edited 30/03/2011	**Condition category** Pregnancy and Childbirth	

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 polyhydraminos
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
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Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
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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