

Medical treatment of retained placenta: does it reduce the number of necessary surgical interventions? A randomised controlled trial in low resource setting

Submission date 02/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/04/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 10/03/2014	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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Treatment of a retained placenta with misoprostol, a double-blind randomised controlled trial in Tanzania

Study objectives

Misoprostol will reduce the amount of manual removals of the placenta.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the National Institute for Medical Research Tanzania on the 27th November 2007 (ref: NIMR/HQ/R.8a/Vol IX/645).

Study design

Double-blind randomised controlled 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 the contact details below to request a patient information sheet (available in Kiswahili and English)

Health condition(s) or problem(s) studied

Retained placenta

Interventions

Study medication will be randomised in blocks and the allocation of sealed envelopes will be in sequence of enrolment. Randomisation of misoprostol to placebo will be 2:1. 30 minutes after delivery of the baby the women will receive study medication sublingually: either misoprostol 800 microgram or placebo.

Duration of follow up: until discharge next day if no complications occur. At discharge patient will be counselled that they have to come back in case of complications (blood loss and/or fever).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome measure

Reduction in the amount of manual removal of placenta (under anaesthesia) 60 minutes after delivery of the baby.

Secondary outcome measures

1. Blood loss
2. Need for blood transfusion

Hb will be checked the morning after the manual removal or the spontaneous expulsion of the placenta. After this it will be decided if a blood transfusion is necessary.

Overall study start date

04/04/2008

Completion date

04/04/2010

Eligibility

Key inclusion criteria

Women with a retained placenta 30 minutes after delivery of the newborn (and a pregnancy duration of at least 28 weeks [birth weight 1 kg]). All women will receive active management of third stage of labour before inclusion.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

117 (39 patients will receive placebo and 78 will receive misoprostol)

Key exclusion criteria

1. Blood loss greater than 750 ml 30 minutes after delivery
2. Pulse rate greater than 120 beats/minute
3. Blood pressure (BP) dropped greater than 20 mmHg diastolic compared with BP before delivery
4. Anaemia (haemoglobin [Hb] less than 100 g/dl). Measurement of third trimester of pregnancy or around delivery

Date of first enrolment

04/04/2008

Date of final enrolment

04/04/2010

Locations

Countries of recruitment

Tanzania

Study participating centre

P.O. Box 228

Lindi

Tanzania

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Sponsor information

Organisation

Tanzanian German Programme to Support Health (TGPSH) (Tanzania)

Sponsor details

P.O. Box 65350

Dar es Salaam

Tanzania

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Sponsor type

Research organisation

Website

<http://www.tgpsh.or.tz>

Funder(s)

Funder type

Research organisation

Funder Name

Tanzanian German Programme to Support Health (TGPSH) (Tanzania) - allows personnel to conduct this study during working hours and will provide transportation, administration and logistics

Funder Name

Radboud University Medical Center (Netherlands) - study medication provided free of charge

Funder Name

The researcher will perform the job unpaid, as will the staff in the joining health facilities.

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?
Protocol article	protocol	23/10/2009		Yes	No
Results article	results	01/09/2013		Yes	No