ISRCTN16104753 https://doi.org/10.1186/ISRCTN16104753

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

Submission date	Recruitment status	[ ] Prospectively registered
02/04/2008	No longer recruiting	[X] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
21/04/2008	Completed	[X] Results
Last Edited	Condition category	[ ] Individual participant data
10/03/2014	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Heleen van Beekhuizen

Contact details
P.O. Box 228
Lindi
Tanzania
-

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 sponteneous 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
-

Sponsor information

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

Sponsor details
P.O. Box 65350
Dar es Salaam
Tanzania
-

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