

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

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

## 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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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.

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Female

## 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)

## 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

### 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?
<a href="#">Results article</a>	results	01/09/2013		Yes	No
<a href="#">Protocol article</a>	protocol	23/10/2009		Yes	No