

Is misoprostol a safe alternative to manual vacuum aspiration in women with incomplete abortions in developing countries?

Submission date 01/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/02/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Is misoprostol a safe alternative to manual vacuum aspiration in women with early pregnancy failure in a low resource setting?: a randomized controlled trial

Study objectives

Misoprostol is just as effective as Manual Vacuum Aspiration (MVA) in treatment of first trimester pregnancy failure, but is more acceptable to clients in a rural setting in low resource countries.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Institute of Medical Research Dar es Salaam, approved on 18 October 2007 (ref: NIMR/HR/R.8a/Vol. IX/628)

Study design

Evaluator-blinded, single-centre, randomised controlled non-inferiority trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Patient information form in Kiswahili is available on request. Please use the contact details below to request.

Health condition(s) or problem(s) studied

First trimester pregnancy failure

Interventions

Misoprostol 600 microgram 3 doses (one dose every 4 hours) sublingually versus MVA

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

misoprostol

Primary outcome measure

Ultrasonographic endometrium thickness at day 8

Secondary outcome measures

The following will be assessed at day 8:

1. Changes in hemoglobin (Hb) level
2. Side effects including pain
3. Adverse events
4. Patients satisfaction and acceptability

If any problem is observed on day 8, the patient will be reviewed again on day 15 (No review at day 15 if no problem is observed).

Overall study start date

11/02/2008

Completion date

11/02/2009

Eligibility**Key inclusion criteria**

1. History of passage of tissue and/or blood and >30 mm endometrial thickness on TransVaginal Sonography (TVS)
2. On TVS an anembryonic gestation or fetal death with an embryonic crown-rump length between 5 and 62 mm without cardiac activity (in case of a Crown-Rump Length [CRL] of 5-9 mm TVS will be repeated after one week to ensure absence of cardiac activity) or an anembryonic gestational sac of 16-45 mm (TVS will be repeated after one week to ensure growth of the gestational sac is <3 mm and exclude a viable pregnancy)

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

180

Key exclusion criteria

1. On TVS present fetal heart activity, a crown-rump length >62 mm, molar pregnancy or a endometrial thickness less than or equal to 30 mm
2. Fundal height of more than halfway the umbilicus and the symphysis indicating a gestational age >12 weeks
3. Known allergy to prostaglandins

4. Heavy blood loss or a pulse rate of >120/min
5. Axillary temperature of > 38°C or signs of septic abortion such as pus draining from uterus
6. Ectopic pregnancy

Date of first enrolment

11/02/2008

Date of final enrolment

11/02/2009

Locations

Countries of recruitment

Tanzania

Study participating centre

PO box 228

Lindi

Tanzania

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Sponsor information

Organisation

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

Sponsor details

Lindi Office

PO box 97

Lindi

Tanzania

-

Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

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

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