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

Submission date	Recruitment status	[ ] Prospectively registered
01/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/02/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/02/2008	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Ultrasonographic endometrium thickness at day 8

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration