

Misoprostol for treating postpartum haemorrhage: a randomised controlled trial

Submission date 19/07/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/07/2004	Overall study status Completed	☐ Protocol
Last Edited 10/08/2007	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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
CRHS010215a

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Postpartum haemorrhage

Interventions

1. Intervention group: Misoprostol 200 µg tablets. Each woman receives 1 tablet orally, 2 tablets sublingually and 2 tablets rectally.

2. Control group: identical placebo tablets. Each woman receives 1 tablet orally, 2 tablets sublingually and 2 tablets rectally.

(All women receive routine accepted treatment for postpartum haemorrhage)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2003

Eligibility**Key inclusion criteria**

Women with postpartum haemorrhage defined as vaginal bleeding after childbirth considered to be excessive, and considered likely to be due to inadequate uterine contraction

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2002

Date of final enrolment

01/12/2003

Locations

Countries of recruitment

South Africa

Study participating centre

P Bag X9047

East London

South Africa

5201

Sponsor information

Organisation

University of the Witwatersrand (South Africa)

ROR

<https://ror.org/03rp50x72>

Funder(s)

Funder type

University/education

Funder Name

University of the Witwatersrand (South Africa) - No external funding; this trial was funded from the existing research unit budget, using full-time research staff.

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?
Results article	Results	06/08/2004		Yes	No