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Misoprostol for treating postpartum haemorrhage: a randomised controlled trial

Submission date
19/07/2004

Recruitment status
No longer recruiting

Registration date
20/07/2004

Overall study status
Completed

Last Edited
10/08/2007

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

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
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Sponsor information

Organisation
University of the Witwatersrand (South Africa)

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Sponsor type
University/education

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

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?
Results article	Results	06/08/2004		Yes	No