ISRCTN34455240 https://doi.org/10.1186/ISRCTN34455240

Misoprostol to treat Postpartum Haemorrhage (PPH): a randomised controlled trial (Argentina, Egypt, South Africa, Thailand and Viet Nam)

Submission date
06/06/2005

Recruitment status
No longer recruiting

Registration date
07/06/2005

Overall study status
Completed

Last Edited
25/08/2011

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
WHO/A35042

Study information

Scientific Title

Study objectives
To assess the effects of misoprostol adjunct to the use of injectable oxytocics in women requiring additional uterotonics following active management of the third stage of labour, on outcomes such as blood loss and side effects.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Postpartum haemorrhage

Interventions
Women will be provided with information about the trial during antenatal care. At admission for delivery the trial will be explained again and women will be invited to give informed consent. After delivery, women clinically diagnosed with postpartum haemorrhage requiring further uterotonic treatment will be given injectable uterotonics as routinely practised at each centre. Women with PPH who agreed to participate in the trial will be randomized and will be given the trial's treatment (3 tablets of misoprostol 200 µg or placebo). The three tablets will be administered sublingually. The administration of the study medication (misoprostol or placebo) will be as close to the administration of additional injectable uterotonics as possible.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Misoprostol

Primary outcome measure
The primary outcome will be the incidence of greater than or equal to 500 ml of measured blood loss at 60 minutes after enrolment.

Follow up duration for primary endpoints: approximate duration of involvement in the study for each subject is one follow up visit 10 days post-treatment.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2005

Completion date
31/10/2006

Eligibility

Key inclusion criteria
All women delivering vaginally with clinically diagnosed PPH thought to be due to or contributed to by atonia requiring additional uterotonics will receive either misoprostol or placebo in addition to routine treatment for PPH.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1400

Key exclusion criteria
Refusal to give consent for participation; Too ill or distressed to give consent; The woman is not entitled to give informed consent e.g. minors without a guardian; The delivery is regarded as abortion according to the local gestational age limits; If the woman is delivered by caesarean section; If the woman cannot take misoprostol sub-lingually; If the woman suffers from severe bleeding disorder such as haemophilia; If the woman has a temperature of more than 38.5°C; If the woman has any severe allergic condition; If the woman's placenta is not delivered at the time of randomization.

Date of first enrolment

01/05/2005

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Argentina

Egypt

South Africa

Switzerland

Thailand

Viet Nam

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction

Sponsor details
World Health Organisation
20 Avenue Appia
Geneva-27
Switzerland
CH-1211

Sponsor type
Research organisation

Website
http://www.who.int/reproductive-health/hrp/

ROR

https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA) /World Health Organization (WHO)/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Funder Name
Gynuity Health Projects will be responsible for funding and financial oversight of the centres

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	22/05/2010		Yes	No