

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

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>06/06/2005   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>07/06/2005 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>25/08/2011       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input checked="" type="checkbox"/> Results          |
|                                        |                                                       | <input type="checkbox"/> 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**

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 22/05/2010   |            | Yes            | No              |