

# Comparison of two routes and two intervals of administration of misoprostol for the termination of early pregnancy: a randomised multicentre trial

<b>Submission date</b> 19/03/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/04/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/10/2014	<b>Condition category</b> 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

**Protocol serial number**  
WHO/HRP ID A05217

## Study information

**Scientific Title**

**Study objectives**

To investigate the feasibility of the misoprostol-only regimen (0.8 mg vaginally or sublingually every 3 hours versus every 12 hours up to three doses).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institutional review boards at all participating hospitals and the World Health Organization (WHO) Secretariat Committee on Research on Human Subjects gave ethics approval.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Induced abortion

**Interventions**

Four treatment groups:

A: Sublingual misoprostol every 3 hours

B: Sublingual misoprostol every 12 hours

C: Vaginal misoprostol every 3 hours

D: Vaginal misoprostol every 12 hours

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Misoprostol

**Primary outcome(s)**

Effectiveness, induction to abortion interval, side effects and acceptability.

Approximate duration of involvement in the study for each subject: first follow-up at 15 days post-treatment, second follow-up (if required) at 42 days, subsequent follow-up as needed.

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

01/12/2002

## Eligibility

### Key inclusion criteria

1. Healthy women, eligible for and requesting medical abortion
2. Agrees to surgical termination should method fail

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### Key exclusion criteria

1. Any indication of serious past or present illness
2. Allergic to misoprostol or with a strong allergic tendency in general
3. Heavy smokers (greater than 20 cigarettes a day)
4. With a scar in the uterus or cervix or any gynaecological anomaly detected with ultrasound
5. A history or evidence of mitral stenosis, glaucoma, or sickle cell anaemia
6. Diastolic blood pressure greater than 90 mmHg
7. Uncontrolled bronchial asthma
8. Systolic blood pressure less than 90 mmHg
9. History or evidence of thromboembolism or liver disease
10. Presence of an intrauterine device in utero
11. Haemolytic disorders

### Date of first enrolment

01/12/2001

### Date of final enrolment

01/12/2002

## Locations

### Countries of recruitment

Armenia

Cuba

Georgia

India

Mongolia

Switzerland

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

### 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)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	09/06/2007		Yes	No
<a href="#">Results article</a>	results	01/06/2012		Yes	No