

# Comparison of two mifepristone doses and two misoprostol intervals for early pregnancy termination

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| <b>Submission date</b><br>22/03/2004   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>01/04/2004 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>27/10/2022       | <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/ HRP ID A15078

# Study information

## Scientific Title

Comparison of two mifepristone doses and two misoprostol intervals for early pregnancy termination

## Study objectives

To compare two doses of mifepristone, 100 mg and 200 mg, followed by 0.8 mg vaginal misoprostol either 24 or 48 hours later in terms of effectiveness, side-effects and duration of bleeding. The objective is to investigate whether the dose of mifepristone can be lowered to 100 mg (double-blind) and whether the interval of 48 hours between mifepristone and misoprostol can be shorted to 24 hours without decreasing efficacy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. SERG - Scientific and Ethical Review Group at WHO
2. SCRIHS - Scientific Committee on Research in Human Subjects

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Induced abortion

## Interventions

Four treatment regimens:

1. 100 mg mifepristone followed 24 hours later by misoprostol
2. 100 mg mifepristone followed 48 hours later by misoprostol
3. 200 mg mifepristone followed 24 hours later by misoprostol
4. 200 mg mifepristone followed 48 hours later by misoprostol

All administered vaginally.

Approximate duration of involvement in the study for each subject: 43 days (second and last follow-up visit), subsequent follow-up if needed.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Mifepristone, misoprostol

**Primary outcome measure**

1. Effectiveness to induce complete abortion in relation to length of amenorrhoea
2. Side effects
3. Duration of bleeding

**Secondary outcome measures**

The frequency of side-effects, in particular the occurrence of lower abdominal pain:

1. Nausea, measured between Mifepristone and Misoprostol regimen, within 3 hours after Misoprostol and after Misoprostol up to 1st follow-up visit
2. Vomiting, measured between Mifepristone and Misoprostol regimen, within 3 hours after Misoprostol and after Misoprostol up to 1st follow-up visit
3. Lower Abdominal Pain, measured between Mifepristone and Misoprostol regimen, within 3 hours after Misoprostol and after Misoprostol up to 1st follow-up visit
4. Diarrhoea, measured between Mifepristone and Misoprostol regimen, within 3 hours after Misoprostol and after Misoprostol up to 1st follow-up visit
5. Headache, measured between Mifepristone and Misoprostol regimen, within 3 hours after Misoprostol and after Misoprostol up to 1st follow-up visit
6. Fever, measured within 3 hours after Misoprostol and after Misoprostol up to 1st follow-up visit
7. Chills/shivering, measured within 3 hours after Misoprostol

**Overall study start date**

01/12/2001

**Completion date**

01/12/2002

**Eligibility****Key inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

1500

**Total final enrolment**

2181

**Key exclusion criteria**

Any indication of past or present ill health will be considered a contraindication for recruitment to the study. In particular, subjects should not be recruited if any of the following conditions are present:

1. Allergy towards mifepristone or misoprostol
2. A history or evidence of disorders that represent a contraindication to the use of:
  - 2.1. Mifepristone (chronic adrenal failure, known allergy to mifepristone, severe asthma uncontrolled by corticosteroid therapy, inherited porphyria)
  - 2.2. Prostaglandins (mitral stenosis, glaucoma, sickle cell anaemia, diastolic pressure over 90 mmHg, bronchial asthma, systolic blood pressure lower than 90 mmHg)
3. A history or evidence of thrombo-embolism, severe or recurrent liver disease
4. Has a medical condition or disease that requires special treatment, care or precaution (e.g. corticosteroid or anticoagulant therapy) in conjunction with abortion
5. Uterine fibroids are relative contraindication (women with fibroids that are likely to affect bleeding or contractility should be excluded)
6. The presence of an Intra-Uterine Device (IUD) in utero (if IUD can easily be removed from the uterus before administration of mifepristone, subject can be included) breast-feeding previous surgery of uterus/uterine cervix is a relative contraindication

In addition, a woman should not be recruited for the study if she is:

7. A heavy smoker (i.e. smoking more than 20 cigarettes daily) or has another risk factor for cardiovascular disease

**Date of first enrolment**

01/12/2001

**Date of final enrolment**

01/12/2002

**Locations**

**Countries of recruitment**

Bosnia and Herzegovina

China

Croatia

Hungary

Mongolia

Montenegro

North Macedonia

Romania

Serbia

Slovenia

South Africa

Sweden

Switzerland

Viet Nam

Zambia

**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 Organization  
20 Avenue Appia  
Geneva-27  
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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)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## 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> |         | 21/01/2009   | 27/10/2022 | Yes            | No              |