

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

Submission date 22/03/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/04/2004	Overall study status Completed	☐ Protocol
Last Edited 27/10/2022	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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
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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

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?
Results article		21/01/2009	27/10/2022	Yes	No