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

Submission date	Recruitment status	[_] Prospectively registered
22/03/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/04/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2022	Pregnancy and Childbirth	

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