

A double-blind, randomised, controlled multicentre trial of three misoprostol regimens after pretreatment with mifepristone for termination of early pregnancy

Submission date 19/03/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/04/2004	Overall study status Completed	☐ Protocol
Last Edited 31/05/2011	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 97903

Study information

Scientific Title

Study objectives

To compare three treatment regimens of misoprostol when used after pretreatment with mifepristone for the termination of early pregnancy in women with the length of amenorrhoea of up to 63 days.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received for all centres before participant recruitment.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Induced abortion

Interventions

All women treated with a single dose of 200 mg mifepristone on Day 1.

Day 3:

Group A: 0.8 mg misoprostol orally and placebo tablets vaginally.

Groups B and C: 0.8 mg misoprostol vaginally and placebo tablets orally.

Groups A and B will continue with 0.4 mg oral misoprostol twice daily on Days 4 - 10.

Group C: placebo tablets twice daily on Days 4 - 10.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misoprostol, mifepristone

Primary outcome(s)

Three treatment regimens will be compared in terms of:

1. Their effectiveness to induce complete abortion
2. The frequency of side effects
3. The duration of bleeding

Approximate duration of involvement in the study for each subject: second follow-up visit on day 43 post treatment, third follow-up visit if required

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/12/2000

Eligibility

Key inclusion criteria

1. Healthy women
2. Eligible for and requesting medical abortion
3. Prepared to terminate the pregnancy should the treatment fail

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/09/1998

Date of final enrolment

01/12/2000

Locations

Countries of recruitment

China

Finland

Hong Kong

Hungary

India

Mongolia

Norway

Romania

Singapore

Slovenia

Sweden

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 (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

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?
Results article	results	01/07/2004		Yes	No