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

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
19/03/2004		☐ Protocol		
Registration date 01/04/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
31/05/2011	Pregnancy and Childbirth			

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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## Contact details

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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.

## 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

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 measure

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

## Secondary outcome measures

No secondary outcome measures

## Overall study start date

01/09/1998

## 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** 

## Age group

Adult

## Sex

**Female** 

## Target number of participants

2100

## Key exclusion criteria

No exclusion criteria

## Date of first enrolment

01/09/1998

## Date of final enrolment

# 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

# Sponsor information

## Organisation

Switzerland CH-1211

UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

# Sponsor details

World Health Organization 20 Avenue Appia

Geneva-27 Switzerland 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

# 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