

Misoprostol administered sublingually for second trimester pregnancy termination

Submission date 19/03/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/04/2004	Overall study status Completed	☐ Protocol
Last Edited 11/12/2008	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

Contact name
Dr Helena von Hertzen

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
vonhertzenh@who.int

Additional identifiers

Protocol serial number
WHO/HRP ID A15065

Study information

Scientific Title

Study objectives

To compare two treatment regimens (0.4 mg misoprostol administered sublingually versus vaginally every three hours up to five doses) for the termination of pregnancy in women with a length of amenorrhoea between 14 to 20 weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Induced abortion

Interventions

Misoprostol (0.4 mg) either vaginally or sublingually every three hours up to five doses.

Approximate duration of involvement in the study for each subject: first follow up at 15 days post-treatment, another follow-up visit will be carried out according to the practice of the hospital.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

1. The effectiveness to induce complete or partial abortion/induction-to-abortion interval
2. The frequency of side effects
3. Acceptability of treatment to women

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/12/2002

Eligibility

Key inclusion criteria

1. Healthy women
2. Eligible for and requesting legal termination of second trimester pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/12/2001

Date of final enrolment

01/12/2002

Locations

Countries of recruitment

Armenia

Georgia

Hungary

India

Slovenia

South Africa

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

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	01/09/2004		Yes	No
Results article	results	01/01/2009		Yes	No