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Misoprostol administered sublingually for second trimester pregnancy termination

Submission date	Recruitment status	[_] Prospectively registered
19/03/2004	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
11/12/2008	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 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

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
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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2001

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

Age group
Adult

Sex
Female

Target number of participants
680

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

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

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