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Pretreatment with vaginal misoprostol before vacuum aspiration

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
10/10/2014	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 A15066

Study information

Scientific Title

Study objectives
To evaluate if vaginal administration of 0.4 mg misoprostol facilitates cervical dilation, reduces complications of first trimester induced abortion, and is acceptable to women.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Induced abortion

Interventions
Misoprostol (0.4 mg) versus placebo tablet three hours before vacuum aspiration. Approximate duration of involvement in the study for each subject is one follow up visit ten days post-treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Misoprostol

Primary outcome measure

Will evaluate if preoperative treatment with 0.4 mg misoprostol administered vaginally three hours before vacuum aspiration can reduce complications of surgical first trimester abortion.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2001

Completion date
01/12/2002

Eligibility

Key inclusion criteria
1. Pregnancy of less than 12 completed weeks
2. Be informed about the study and sign a consent form
3. Agree to return for a follow-up visit five to ten days after surgery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
4464

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

China

Cuba

Hungary

India

Mongolia

Romania

Slovenia

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

Sponsor details
World Health Organization
20 Avenue Appia
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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	12/05/2012		Yes	No