ISRCTN85366519 https://doi.org/10.1186/ISRCTN85366519

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

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 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
No secondary outcome measures

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

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

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

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	12/05/2012		Yes	No