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

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## 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |