A double-blind, randomised, controlled multicentre trial of misoprostol treatment prior to Vacuum Aspiration for termination of early pregnancy

Submission date	Recruitment status	Prospectively registered
17/04/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
03/05/2007	Completed	Results
Last Edited	Condition category	Individual participant data
10/10/2014	Pregnancy and Childbirth	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number A15066

Study information

Scientific Title

Acronym

Cervical priming prior to VA

Study objectives

Null hypothesis:

There is no difference between first trimester abortion with and without pre-abortion priming of the cervix with 400 micrograms of misoprostol with regard to all complications associated with abortion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the SCRIHS (Scientific Committee for Research in Human Subjects) and local ethics committees at each participating centre. SCRIHS approved the protocol of this Project A15066 on 23/07/2001

Study design

Randomised placebo-controlled multicentre clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Termination of early pregnancy by vacuum aspiration

Interventions

Two tablets of 200 micrograms of misoprostol or two placebo tablets will be administered vaginally three hours before vacuum aspiration. Type of analgesia/anaesthesia, baseline cervical dilation, duration of procedure, amount of bleeding, complications during and after procedure, etc., will be recorded. A follow-up visit is scheduled 7 to 10 days after vacuum aspiration.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

Complication rates in misoprostol and placebo groups, measured during the procedure, in the immediate post-operative period, and up until the follow-up visit 7 to 14 days after the procedure

Key secondary outcome(s))

- 1. Ease of the procedure (dilation, duration of procedure, pain level), measured during the procedure
- 2. Side-effects, measured at any time after administration of misoprostol until the end of the study

Completion date

24/09/2005

Eligibility

Key inclusion criteria

- 1. Women requesting abortion and eligible for legal termination of normal single intrauterine pregnancy of less than 12 completed weeks (84 days) of gestation
- 2. Consent to participation
- 3. Able to understand information on the study
- 4. Agree to return for the scheduled follow-up visit

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Women are not eligible if they have:

- 1. A medical condition or disease that requires special treatment, care of precautions in conjunction with vacuum aspiration
- 2. Allergy to misoprostol
- 3. Contraindications to misoprostol
- 4. Anaemia or any coagulation disorder

Date of first enrolment

21/10/2002

Date of final enrolment

24/09/2005

Locations

Countries of recruitment

Armenia

China

Hungary		
India		
Mongolia		
Romania		
Slovenia		
Switzerland		
Viet Nam		

Study participating centre

Department of Reproductive Health and Research

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

Cuba

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 summaryNot provided at time of registration