Comparison of two routes and two intervals of administration of misoprostol for the termination of early pregnancy: a randomised multicentre trial

Submission date	Recruitment status	Prospectively registered		
19/03/2004	No longer recruiting	☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
01/04/2004		[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 A05217

Study information

Scientific Title

Study objectives

To investigate the feasibility of the misoprostol-only regimen (0.8 mg vaginally or sublingually every 3 hours versus every 12 hours up to three doses).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional review boards at all participating hospitals and the World Health Organization (WHO) Secretariat Committee on Research on Human Subjects gave ethics approval.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Induced abortion

Interventions

Four treatment groups:

A: Sublingual misoprostol every 3 hours

B: Sublingual misoprostol every 12 hours

C: Vaginal misoprostol every 3 hours

D: Vaginal misoprostol every 12 hours

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

Effectiveness, induction to abortion interval, side effects and acceptability.

Approximate duration of involvement in the study for each subject: first follow-up at 15 days post-treatment, second follow-up (if required) at 42 days, subsequent follow-up as needed.

Key secondary outcome(s))

No secondary outcome measures

Completion date

Eligibility

Key inclusion criteria

- 1. Healthy women, eligible for and requesting medical abortion
- 2. Agrees to surgical termination should method fail

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

- 1. Any indication of serious past or present illness
- 2. Allergic to misoprostol or with a strong allergic tendency in general
- 3. Heavy smokers (greater than 20 cigarettes a day)
- 4. With a scar in the uterus or cervix or any gynaecological anomaly detected with ultrasound
- 5. A history or evidence of mitral stenosis, glaucoma, or sickle cell anaemia
- 6. Diastolic blood pressure greater than 90 mmHg
- 7. Uncontrolled bronchial asthma
- 8. Systolic blood pressure less than 90 mmHg
- 9. History or evidence of thromboembolism or liver disease
- 10. Presence of an intrauterine device in utero
- 11. Haemolytic disorders

Date of first enrolment

01/12/2001

Date of final enrolment

01/12/2002

Locations

Countries of recruitment

Armenia

Cuba

Georgia

India

Mongolia

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	09/06/2007		Yes	No
Results article	results	01/06/2012		Yes	No