

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

Submission date 19/03/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/04/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/10/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/12/2001

Completion date

01/12/2002

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

Age group

Adult

Sex

Female

Target number of participants

2100

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

Sponsor details

World Health Organization

20 Avenue Appia

Geneva-27

Switzerland

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