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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/04/2004	**Overall study status** Completed	
Last Edited 10/10/2014	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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