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

Submission date
17/04/2007

Recruitment status
No longer recruiting

Registration date
03/05/2007

Overall study status
Completed

Last Edited
10/10/2014

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
21/10/2002

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

Age group
Adult

Sex
Female

Target number of participants
4984

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

Cuba

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

Sponsor details
Department of Reproductive Health and Research
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211

Sponsor type
Research organisation

Website
http://www.who.int/reproductive-health/hrp/index.htm

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