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Comparison of two doses and two routes of administration of misoprostol after pre-treatment with mifepristone for early pregnancy termination: a randomised, placebo-controlled, multicentre trial

Submission date
04/05/2006

Registration date
04/05/2006

Last Edited
27/10/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
A35148

Study information

Scientific Title
Comparison of two doses and two routes of administration of misoprostol after pre-treatment with mifepristone for early pregnancy termination: a randomised, placebo-controlled, multicentre trial

Study objectives
Our hypothesis is that the efficacy of the 0.4 mg dose of misoprostol, whether given sublingually or vaginally after mifepristone pre-treatment, is not inferior to that of the 0.8 mg dose of misoprostol within a margin of 3%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received on the 24th May 2005.

Study design
A randomised, placebo-controlled, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Termination of early pregnancy

Interventions
200 mg mifepristone orally on Day 1 of the study followed 36 - 48 hours later by:
1. Four placebo tablets vaginally and two tablets of 0.2 mg misoprostol sublingually followed by two placebo tablets sublingually 20 minutes later
2. Four placebo tablets vaginally and two tablets of 0.2 mg misoprostol sublingually followed by another two sublingual misoprostol tablets of 0.2 mg 20 minutes later
3. Two tablets of 0.2 mg of misoprostol and two placebo tablets vaginally and two placebo

tablets sublingually followed by another two placebo tablets sublingually 20 minutes later
4. Four tablets of misoprostol vaginally and two tablets of placebo sublingually followed by another two placebo tablets sublingually 20 minutes later

Women return to follow-up visits two weeks and six weeks after mifepristone administration.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Misoprostol, mifepristone

Primary outcome measure
The four regimens will be compared in respect of the following main outcomes:
1. Their effectiveness to induce complete abortion
2. Induction-to-abortion interval, when possible
3. The occurrence of side-effects
4. Women's perceptions

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2006

Completion date
01/09/2007

Eligibility

Key inclusion criteria
A total of 2880 subjects (192 women at each of the 15 participating centres) will be recruited from among women requesting legal termination of pregnancy. Participants will satisfy the following criteria:
1. Good general health
2. Older than the age of legal consent
3. Requesting abortion and eligible for legal termination of pregnancy
4. On Day 1 of the study (day of mifepristone administration) the duration of pregnancy not more than 63 days (counted from the first day of the last menstrual period) in a normal 28-day cycle
5. The duration of the pregnancy corresponds to the length of amenorrhoea when verified with ultrasound; if the gestational length according to ultrasound measurements differs more than 4 days, the ultrasound dating should be used
6. The pregnancy is single and intrauterine (single sac)
7. If treatment with misoprostol should fail, agrees to surgical termination of pregnancy
8. Willing and able to participate (return to follow-up!) after the study has been explained
9. Haemoglobin higher than 90 g/l

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2880

Total final enrolment
3005

Key exclusion criteria
1. Any indication of serious past or present ill health will be considered a contraindication for recruitment to the study
2. In particular, subjects should not be recruited if any of the following conditions are present:
2.1. Allergy towards mifepristone or misoprostol
2.2. A history or evidence of disorders that represent a contraindication to the use of mifepristone (chronic adrenal failure, known allergy to mifepristone, severe asthma uncontrolled by corticosteroid therapy, inherited porphyria) or prostaglandins (mitral stenosis, sickle cell anaemia, diastolic pressure over 90 mmHg, systolic blood pressure lower than 90 mmHg measured with a traditional instrument)
2.3. A history or evidence of thrombo-embolism, severe or recurrent liver disease
2.4. Has a medical condition or disease that requires special treatment, care or precaution (e.g. corticosteroid or anticoagulant therapy) in conjunction with abortion
2.5. Uterine fibroids are relative contraindication (women with fibroids that are likely to affect bleeding or contractility should be excluded)
2.6. The presence of an intrauterine device (IUD) in utero
2.7. Breastfeeding
2.8. Previous surgery of uterus/uterine cervix is a relative contraindication. However, previous low-segment caesarean section does not need to be a contraindication.
2.9. Suspicion of any pathology of pregnancy (e.g. mola, non-viable pregnancy, threatened abortion)
2.10. In case difficulties are anticipated in the follow-up of the woman (e.g. lives too far)
3. Women older than 35 years can be recruited for the present trial provided they do not smoke, their diastolic blood pressure is less than 90 mmHg and have no known risk factor for cardiovascular disease

Date of first enrolment
01/09/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment

China

Cuba

Georgia

India

Mongolia

Serbia

Slovenia

Switzerland

Viet Nam

Study participating centre
Department of Reproductive Health and Research
Geneva-27
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Sponsor information

Organisation
UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction

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Sponsor type
Research organisation

Website
http://www.who.int

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/06/2008	06/01/2021	Yes	No
Results article		01/09/2010	27/10/2022	Yes	No