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A double-blind, randomised, controlled multicentre trial of three misoprostol regimens after pretreatment with mifepristone for termination of early pregnancy

Submission date
19/03/2004

Recruitment status
No longer recruiting

Registration date
01/04/2004

Overall study status
Completed

Last Edited
31/05/2011

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] 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

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 97903

Study information

Scientific Title

Study objectives
To compare three treatment regimens of misoprostol when used after pretreatment with mifepristone for the termination of early pregnancy in women with the length of amenorrhoea of up to 63 days.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received for all centres before participant recruitment.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Induced abortion

Interventions
All women treated with a single dose of 200 mg mifepristone on Day 1.

Day 3:
Group A: 0.8 mg misoprostol orally and placebo tablets vaginally.
Groups B and C: 0.8 mg misoprostol vaginally and placebo tablets orally.

Groups A and B will continue with 0.4 mg oral misoprostol twice daily on Days 4 - 10.
Group C: placebo tablets twice daily on Days 4 - 10.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Three treatment regimens will be compared in terms of:
1. Their effectiveness to induce complete abortion
2. The frequency of side effects
3. The duration of bleeding

Approximate duration of involvement in the study for each subject: second follow-up visit on day 43 post treatment, third follow-up visit if required

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/12/2000

Eligibility

Key inclusion criteria
1. Healthy women
2. Eligible for and requesting medical abortion
3. Prepared to terminate the pregnancy should the treatment fail

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
No exclusion criteria

Date of first enrolment
01/09/1998

Date of final enrolment
01/12/2000

Locations

Countries of recruitment
China

Finland

Hong Kong

Hungary

India

Mongolia

Norway

Romania

Singapore

Slovenia

Sweden

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 (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

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	01/07/2004		Yes	No