ISRCTN49711898 https://doi.org/10.1186/ISRCTN49711898

Medical abortion at 10-20 weeks

Submission date
22/08/2013

Recruitment status
No longer recruiting

Registration date
02/10/2013

Overall study status
Completed

Last Edited
17/12/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Two drugs, mifepristone and misoprostol, are authorized to use for the termination of an early pregnancy only, although they are recommended as the best and safest method by the World Health Organization, and also used, unlicensed, for the termination of later stages of pregnancies. Clinical trial data is needed for registration but these data are not currently available. The purpose of this study is to demonstrate how this drug regimen works and how to use the information to officially register the method.

Who can participate?
Women who are 64 to 140 days pregnant can participate in the study.

What does the study involve?
Women will first get a pill of mifepristone to swallow, and when they return to the hospital one or two days later, they will be given the second drug, misoprostol. They may need two to three doses of misoprostol. They are given at 3-hour intervals, before the pregnancy is terminated.

What are the possible benefits and risks of participating?
Some women prefer medical abortion to surgical abortion so this study may give them this choice. Most women in the study can be expected to have a complete abortion and will not be exposed to some of the risks associated with surgical abortion, particularly the risk of physical distress. By participating in the study women do not increase their risks associated with the termination of pregnancy.

Where is the study run from?
The study will be run from eight hospitals in India, Sweden, Thailand and Vietnam.

When is the study starting and how long is it expected to run for?
We expect to start the study by the end of 2013 and it is expected to last for 12-14 months.

Who is funding the study?
Concept Foundation, Geneva, Switzerland.

Who is the main contact?
Dr Helena von Hertzen
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2013-004294-27

Study information

Scientific Title
Termination Of Pregnancy at 64-140 days

Acronym
TOP

Study objectives
Administration of misoprostol 24 h after mifepristone is non-inferior in efficacy, measured as abortion rate at 24 h, to administration of misoprostol 48 h after mifepristone, assuming that this rate in both interval groups will be about 96%-97% and within an inferiority margin of 5%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board, Faculty of Medicine, Chulalongkorn University, Thailand, 20/03/2014
2. Committee on Human Rights Related to Research Involving Human Subjects, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand, 22/01/2014
3. Siriraj Institutional Review Board, Thailand, 21/05/2014

Primary study design
Interventional

Study design
International multicentre trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Pregnancy of 64-140 days duration

Interventions
Women are randomized to receive misoprostol treatment (orally) (as in WHO Safe abortion guidelines, 2012) either 24 hours or 48 hours after mifepristone.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Efficacy (expulsion of pregnancy) at 24 h

Key secondary outcome(s)
1. Induction-to-abortion interval: This is the time interval from the administration of the first dose of misoprostol until expulsion of the products of conception
2. Possible side-effects: Side effects are recorded during the whole study, from the administration of mifepristone until the follow-up visit, or beyond, if needed
3. Women's perceptions: Women's perception of the method are recorded at an interview during the follow-up visit about two weeks after treatment

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Good general health
2. Older than the age for legal consent
3. Requesting and eligible for legal termination of pregnancy
4. Duration of pregnancy 64-140 days on Day 1 (mifepristone administration), verified by ultrasound

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. No contra-indications towards mifepristone and misoprostol
2. No serious present or past ill health
3. Molar or extrauterine pregnancy or threathend abortion, >1 low segment C-section

Date of first enrolment
01/01/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
India

Sweden

Switzerland

Thailand

Viet Nam

Study participating centre
46 Route de Montfleury
Geneva
Switzerland
1214

Sponsor information

Organisation
Concept Foundation (Switzerland)

ROR
https://ror.org/039k72k82

Funder(s)

Funder type
Charity

Funder Name
Concept Foundation (Switzerland)

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?
Protocol file		03/10/2013	17/12/2024	No	No