

# Medical abortion at 10-20 weeks

<b>Submission date</b> 22/08/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
helena.vonhertzen@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Helena von Hertzen

**Contact details**  
46 Route de Montfleury  
Geneva  
Switzerland  
1214

## Additional identifiers

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

**Protocol serial number**  
N/A

## 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

**Study design**

International multicentre trial

**Primary study design**

Interventional

**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?
<a href="#">Protocol file</a>		03/10/2013	17/12/2024	No	No