

# Comparing efficacy of vaginal misoprostol administered at 6-8 hours with 24 hours administration after 200 mg of oral mifepristone for early medical abortions

<b>Submission date</b> 18/02/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/05/2017	<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:

An abortion is the deliberate termination of a pregnancy, most often performed during the first 28 weeks of pregnancy. In May 2010, the Department of Health released the latest abortion statistics. Total number of abortions in England and Wales were 189,100 in 2009, compared with 195,296 in 2008, a fall of 3.2%. Abortion rate was highest in women aged 19-21, whilst rates under-16 and under-18 were lower. 91% of abortions were carried out in women up to 13 weeks pregnant and 75% up to 10 weeks. Medical abortions accounted for 40% of the total. It is clear from this data that abortion treatments continue to be provided on a large scale. Newer methods are continuing to be developed to provide women with safe and effective methods. Interestingly not all methods are acceptable to all women and therefore the question of patients' preferences and acceptance poses a clinical dilemma. The few studies that explored shorter time intervals show conflicting evidence have resulted in a large variation in clinical practice for administration of medications at different time intervals for medical abortions. The aim of this study is to assess the acceptability and success of shorter time interval treatments compared to standard time intervals treatments as well as exploring women's perceptions and views through interviews.

### Who can participate?

Adult women who are requesting an abortion

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive the standard treatment regimen, involving misoprostol (a medication used to start labour) being given vaginally 24 hours after being given mifepristone (a medication used to bring about abortion). Those in the second group receive the same treatment but with a 6-8 hour window instead of 24 hours. Participants in both groups are followed up for two weeks to find out how acceptable the treatment they receive is.

What are the possible benefits and risks of participating?  
There are no direct benefits or risks involved with participating.

Where is the study run from?  
Calthorpe Clinic (UK)

When is study starting and how long is it expected to run for?  
April 2009 to June 2011

Who is funding the study?  
Calthorpe Clinic (UK)

Who is the main contact?  
Professor Janesh Kumar Gupta  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Janesh Kumar Gupta

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## Additional identifiers

**EudraCT/CTIS number**  
2009-010277-21

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
TIMES/09-012/11

## Study information

**Scientific Title**

A randomised controlled trial on Efficacy of mifepristone followed by 6-8 hours versus 24 hours vaginal misoprostol in Early Medical Abortions (< 63 days gestation)

**Acronym**

TIMES Study (Time Interval for Medical Early abortionS)

**Study objectives**

The hypothesis for this study is to determine the efficacy of shorter time intervals of administration of misoprostol and also to assess the reliability of follow-up methods to confirm completeness of medical abortion. To explore womens beliefs and preferences to different medical methods within the framework of the randomised controlled trial.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Research Ethics Committee and South Birmingham PCT, 22/06/2009, ref: 09/H1208/22

**Study design**

Non-inferiority randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Early medical abortion

**Interventions**

Participants are randomised to one of two groups using computerised randomisation

Control group: Participants receive the standard treatment regimen of 800mcg of misoprostol as vaginal route 24 hours following administration of 200mg of mifepristone

Intervention group: Participants receive 800 ug of misoprostol given vaginally after 200 mg of mifepristone at 6-8 hours interval or 24 hours interval.

All women will be followed up to a period of 2 weeks.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Proportion of complete abortions where no further medical or surgical intervention beyond the initial dose of vaginal misoprostol required was measured using patient acceptability questionnaire and ultrasound confirmation at the end of 2 weeks.

**Secondary outcome measures**

1. Induction to abortion interval is measured using based on the duration of pain and bleeding at 2 weeks follow up
2. Adverse effects is measured using Likert scale at 2 weeks follow up
3. Pain is measured using VAS at 2 weeks follow up
4. Duration of Bleeding is measured using the No.of hours or days at 2 weeks follow up
5. Acceptability of women towards the new regimen is measured using Likert scale at the 2 weeks follow up
6. Assess reliability of follow-up methods following medical abortion is measured using telephone follow up at 1 week and Urinary quantification of hCG at baseline.2 weeks

For the purpose of qualitative study face to face in depth interviews were conducted at the end of 2 weeks

**Overall study start date**

01/04/2009

**Completion date**

01/06/2011

**Eligibility****Key inclusion criteria**

1. Ability to give informed written consent
2. Women who are 18 years and older
3. Requesting abortion and eligible for legal termination of pregnancy
4. Duration of pregnancy not more than 63 days (counted from the first day of the last menstrual period) in a normal 28-day cycle or verified by ultrasound
5. The pregnancy is single and intrauterine (single sac)
6. Agree to be able to be contacted by telephone (i.e. mobile telephone)
7. Women with limited understanding of English will be included only in the quantitative study where interpreters are available

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

1,200

**Key exclusion criteria**

1. Any indication of serious past or present ill health will be considered a contraindication for recruitment to the study
2. Suspicion of any pathology of pregnancy (e.g. molar, non-viable pregnancy, threatened abortion)
3. Current participation in a drug-related trial
4. Non-English-speaking women for the qualitative study
5. Women under the age of 18 years

**Date of first enrolment**

15/09/2009

**Date of final enrolment**

15/12/2010

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Calthorpe Clinic**

4 Arthur Road

Edgbaston

Birmingham

United Kingdom

B15 2UL

**Sponsor information****Organisation**

Calthorpe Clinic (UK)

**Sponsor details**

c/o Carolyn Philips  
4 Arthur Road  
Edgbaston  
Birmingham  
England  
United Kingdom  
B15 2UL

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.calthorpe-clinic.co.uk/>

**ROR**

<https://ror.org/007bv1h22>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Calthorpe Clinic (UK)

## Results and Publications

**Publication and dissemination plan**

Intend to plan publication in peer reviewed journal, currently available as part of MD Thesis repository electronically from the University of Birmingham.

**Intention to publish date**

31/12/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository - University of Birmingham thesis repository library =

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No