

# Does patient ambulation affect the induction to abortion internal in early medical termination of pregnancy up to 63 days gestation?

**Submission date**  
29/09/2006

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
29/09/2006

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
30/08/2013

**Condition category**  
Pregnancy and Childbirth

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

N0236173578

# **Study information**

## **Scientific Title**

## **Study objectives**

To investigate if encouraging ambulation following administration of misoprostol reduces the induction-to-abortion interval in termination of first trimester pregnancy up to 9 weeks.

Women requesting early medical termination of pregnancy often cite a desire for a more natural experience as a reason for choosing the method. A reluctance for the abortion to be medicalised often figures largely in their decision making process. An opportunity to accommodate this less intrusive approach is lost when the protocol stipulates that the patient must remain on the hospital ward for the duration of the abortion. Ambulation following misoprostol administration is common but the benefits/disadvantages of this approach have not been investigated.

A prospective randomised trial comparing the progress of ambulatory patients with that of non-ambulatory patients is proposed.

Patients will be recruited from the termination of pregnancy clinic.

Patients requesting early medical termination of first trimester pregnancy up to 9 weeks gestation will be offered the opportunity to participate in the study.

The participants will be randomly assigned to one of two groups. Group one will be required to remain on the ward and for the first hour following misoprostol administration will be confined to the recliner chair in a semi-recumbent position. After misoprostol administration, Group two will be encouraged to mobilise immediately and following a fifteen minute observation period will be encouraged to leave the ward and walk around the hospital. Both patient groups will be encouraged to report first symptoms of cramping and first evidence of bleeding to the supervising nurse on the ward. All patients will be obliged to return to the ward when bleeding commences or after four hours, whichever is sooner. The time that products of conception are passed will be recorded. Data will be collated with respect to gestation and gravida to ensure a like with like comparison. Those patients who do not wish to participate will follow the current protocol which requires them to remain on the ward until the products of conception are passed.

The anxiety level and the anxiety state of patients in both the groups will be assessed by the Spielberger Self-Evaluation questionnaire. The questionnaire will be given to the patients after the administration of misoprostol and will be asked to be filled in by the patient herself. The scores from the individual questions will be totalled and a final score for each patient will be obtained which will be used for statistical analysis to detect any significant difference between both the groups.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Pregnancy and Childbirth: Abortion

**Interventions**

The participants will be randomly assigned to one of two groups. Group one will be required to remain on the ward and for the first hour following misoprostol administration will be confined to the recliner chair in a semi-recumbent position. After misoprostol administration, Group two will be encouraged to mobilise immediately and following a fifteen minute observation period will be encouraged to leave the ward and walk around the hospital. Both patient groups will be encouraged to report first symptoms of cramping and first evidence of bleeding to the supervising nurse on the ward. All patients will be obliged to return to the ward when bleeding commences or after four hours, whichever is sooner. The time that products of conception are passed will be recorded. Data will be collated with respect to gestation and gravida to ensure a like with like comparison. Those patients who do not wish to participate will follow the current protocol which requires them to remain on the ward until the products of conception are passed.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. The induction to abortion interval
2. Hospital in-patient time ie admission to discharge interval

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/2005

**Completion date**

31/10/2006

## Eligibility

**Key inclusion criteria**

Women attending for medical termination of pregnancy of gestation below 63 days. Medical termination of pregnancy at this gestation is known to be a safe and predictable procedure. Patients will be approached at clinic and the study explained verbally and written information outlining the study will be given. Patient involvement will be discussed after mifepristone administration and consent for inclusion in the study obtained. Patients will be able to withdraw from the study at any time.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

200

**Key exclusion criteria**

1. Patients under the age of 16 years
2. Adults with a learning disability
3. Patients whose pregnancy exceeds 63 days gestation

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

31/10/2006

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Pregnancy Advisory Service

London

United Kingdom

SW17 0QT

# Sponsor information

## Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

## Sponsor details

The Department of Health, Richmond House, 79 Whitehall  
London  
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+44 (0)20 7307 2622  
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## Sponsor type

Government

## Website

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Government

## Funder Name

St George's Healthcare NHS Trust (UK) NHS R&D Support Funding

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
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[Results article](#)

results

01/04/2012

Yes

No