

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
Registration date 29/09/2006	Overall study status Completed	☐ Protocol
Last Edited 30/08/2013	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Abortion

Interventions

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Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

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

Funder(s)**Funder type**

Government

Funder Name

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

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	01/04/2012		Yes	No