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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

Registration date
29/09/2006

Overall study status
Completed

Last Edited
30/08/2013

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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

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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?

Results article	results	01/04/2012	Yes	No