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

Submission date
18/02/2009

Recruitment status
No longer recruiting

Registration date
06/03/2009

Overall study status
Completed

Last Edited
25/05/2017

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-010277-21

Protocol serial number
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

Primary study design
Interventional

Study design
Non-inferiority randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
United Kingdom

England

Study participating centre
Calthorpe Clinic
4 Arthur Road
Edgbaston
Birmingham
United Kingdom
B15 2UL

Sponsor information

Organisation
Calthorpe Clinic (UK)

ROR
https://ror.org/007bv1h22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Calthorpe Clinic (UK)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically 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?
HRA research summary			28/06/2023	No	No