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Medical versus surgical termination of pregnancy at 13 - 20 weeks

Submission date 23/02/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2010	**Overall study status** Completed	
Last Edited 01/08/2012	**Condition category** Pregnancy and Childbirth	

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
SCR2000/1

Study information

Scientific Title
A randomised controlled trial comparing medical versus surgical termination of pregnancy at 13 - 20 weeks

Study objectives
Compared to surgical termination of pregnancy (STOP), medical termination of pregnancy (MTOP) would be associated with greater psychological distress at 2 weeks after the procedure, as measured by the Impact of Events Scale (IES) at 13 - 20 weeks gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Ethics Committee of the Newcastle and North Tyneside Health Authority approved on the 26th April 2000 (ref: 2000/63)

Study design
Single centre 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
Termination of unwanted pregnancy

Interventions
Women randomised to STOP:
All nulliparous women and multiparous women greater than 17 weeks' gestation were primed with Gemeprost 1 mg vaginally 3 and 6 hours prior to the anticipated time of STOP. Multiparous women between 13+0 and 16+6 weeks were primed with Gemeprost 1 mg vaginally 3 hours prior to the anticipated time of STOP. All STOPs were performed under general anaesthesia by one experienced surgeon. Cases between 13+0 and 14+6 vacuum aspiration was performed Cases greater than or equal to 15+0 weeks dilatation and evacuation was performed.

Women randomised to MTOP:
Women were given mifepristone 200 mg orally. 36 - 48 hours later misoprostol 800 µg was administered vaginally followed by 400 µg vaginally or orally (depending on amount of vaginal bleeding) every 3 hours up to a maximum of 4 doses. If abortion had not occurred by midnight a further dose of mifepristone 200 mg orally was administered followed by gemeprost 1 mg vaginally 3 hourly from 0800 hours up to a maximum of 5 doses. If abortion had still not occurred by 0800 hours the following morning the MTOP was deemed to have failed and STOP arranged.

All women received periabortion antibiotic prophylaxis with doxycycline 100 mg orally twice daily, commencing on the day prior to abortion. Women having STOP also received metronidazole 1 g rectally at the time of abortion. All women were invited back for follow up at two weeks post-procedure.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Mifepristone, misoprotol

Primary outcome measure
Impact of Event Scale (IES) at two weeks after the procedure. This 15 item scale has 7 intrusion and 8 avoidance items.

Secondary outcome measures
1. Clinical effectiveness of procedure, measured at two weeks post-procedure
2. Complications, measured at two weeks post-procedure
3. Procedure specific symptoms, measured at two weeks post-procedure
4. Acceptability, measured at two weeks post-procedure
5. General health Questionnaire-12 item (GHQ-12), measured at baseline and two weeks post-procedure
6. Hospital Anxiety and Depression Scale (HADS), measured at baseline and two weeks post-procedure
7. Satisfaction with care received before during and after procedure (excellent/very good/good /fair/poor), measured at two weeks post-procedure

Overall study start date
01/05/2000

Completion date
31/01/2004

Eligibility

Key inclusion criteria
1. Women accepted for termination of pregnancy (TOP) under clause C of the Human Fertilisation and Embryology Act (1990) amendment of the Abortion Act (1967)
2. Pregnancies between 13+0 and 19+6 weeks' gestation at the time of abortion

3. Aged over 16 years; women under 16 years of age were eligible for inclusion if deemed Fraser competent by the clinical practitioner and where a parent or guardian was present and also willing to give written consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
130

Key exclusion criteria
1. Foetal congenital abnormality
2. Medical disease precluding MTOP
3. Unable to speak English (less than 5% of women presenting for TOP)

Date of first enrolment
01/05/2000

Date of final enrolment
31/01/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cellular Medicine
Newcastle upon Tyne
United Kingdom
NE2 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
The Freeman Hospital
High Heaton
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England
United Kingdom
NE7 7DN
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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
University/education

Funder Name
Newcastle University (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	01/11/2010		Yes	No