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A pragmatic randomised controlled trial of expectant versus surgical management of first trimester spontaneous miscarriage

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
14/10/2014

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
RDC01676

Study information

Scientific Title

Study objectives
1. Surgical management will be more effective than expectant management in bringing about the complete resolution of pregnancy as measured at one week follow up using the transvaginal ultrasound scan.
2. Expectant management will be associated with less infective morbidity than surgical management.
3. Expectant management and surgical management of miscarriage will result in similar clinical outcomes in term of pain, bleeding, convalescence time and fertility.
4. Surgical management will result in greater psychological morbidity than expectant management although no definite predictions of the magnitude of difference can be made.
5. Expectant management will be more cost effective than surgical management.

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: Pregnancy

Interventions
i. Expectant management
ii. Surgical management

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Clinical Outcomes: Complete resolution of pregnancy will be defined as absence of vaginal bleeding and no evidence of products of conception on the ultrasound scan. The attending clinicians will be blind to the treatment received by the patient.
2. Psychological outcomes. Patients will complete measures of: psychological morbidity (anxiety, depression, somatic symptoms and insomnia) subjective health status, individual quality of life, acceptability and satisfaction with the intervention, adjustment of miscarriage using the Perinatal Grief Scale (Thoedter et al, 1988)

Secondary outcome measures
Clinical Outcomes - secondary:
1. Completed by the research nurse: blood pressure and temperature, haemoglobin and white cell count.
2. Completed by the patient: pain (intensity), bleeding (duration and quantity), convalescence time (days), fertility.

Overall study start date
01/10/2000

Completion date
01/10/2002

Eligibility

Key inclusion criteria
1. Positive urine pregnancy test
2. Clinical symptoms of miscarriage (vaginal bleeding, lower abdominal pain)
3. Ultrasound evidence of retained placental tissue
4. Gestation age less than 13 weeks
5. Written informed consent given

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/10/2000

Date of final enrolment
01/10/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UMDS
London
United Kingdom
SE11 6SP

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

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	01/05/2004		Yes	No