

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

☐ Prospectively registered

☐ Protocol

Registration date
23/01/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/10/2014

Condition category
Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jane Ogden

Contact details

UMDS
Dept of General Practice
80 Kennington Road
London
United Kingdom
SE11 6SP

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

UMDS
London
United Kingdom
SE11 6SP

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

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	01/05/2004		Yes	No