ISRCTN66418282 https://doi.org/10.1186/ISRCTN66418282

Randomised controlled trial of expectant, medical and surgical management of early miscarriage.

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
12/01/2010

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

Contact name
Dr Lindsay Smith

Contact details
East Somerset Research Consortium
Westlake Surgery
High Street
West Coker
United Kingdom
BA22 9AH
+44 (0)1935 862624
research@esrec.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R/29/10.99/Smith

Study information

Scientific Title

Acronym
MIST

Study objectives
Main research question: Which of three management methods (expectant, medical or surgical) of failed first trimester pregnancy (missed or incomplete miscarriage) is associated with least gynaecological infection.

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; miscarriage

Interventions
1. Expectant management
2. Medical management
3. Surgical management

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Gynaecological infection within 14 days of randomisation.

Secondary outcome measures
1. Bleeding & pain
2. Retained products by scan at 10-14 days
3. Depression
4. Anxiety
5. Return to normal activity
6. Complications by 6 weeks

Overall study start date
01/04/1997

Completion date
31/10/2001

Eligibility

Key inclusion criteria
1. Women with a failed pregnancy of <13 weeks gestation
2. Attending the early pregnancy assessment clinics of Southmead Hospital, Bristol or the Royal United Hospital, Bath
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1200 women were recruited: 399 to expectant management, 398 to medical management, and 403 to surgical management (added 12/01/10, see publication)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/04/1997

Date of final enrolment
31/10/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East Somerset Research Consortium
West Coker
United Kingdom
BA22 9AH

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 South West (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	27/05/2006		Yes	No
Other publications	economic evaluation	01/08/2006		Yes	No
Results article	results	08/10/2009		Yes	No