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

Submission date Recruitment status Prospectively registered 23/01/2004 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results [ ] Individual participant data Last Edited Condition category Pregnancy and Childbirth 12/01/2010

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Lindsay Smith

#### Contact details

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# Additional identifiers

# Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

Gynaecological infection within 14 days of randomisation.

## Key secondary outcome(s))

- 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

## Completion date

# **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** 

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

**Female** 

## 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

United Kingdom

England

# 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)

# Funder(s)

# Funder type

Government

## Funder Name

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