

Out-patient management of missed miscarriage: a randomised trial of medical vs medical/minimally invasive management using transcervical amnion rupture

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 02/06/2017	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0024125765

Study information

Scientific Title

Out-patient management of missed miscarriage: a randomised trial of medical vs medical /minimally invasive management using transcervical amnion rupture

Study objectives

The aim of this study is to compare vaginal misoprostol alone against transcervical amniotic puncture followed by vaginal misoprostol in the outpatient management of missed miscarriage.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Miscarriage

Interventions

Vaginal misoprostol (800 mcg) alone against transcervical amniotic puncture followed by vaginal misoprostol (800 mcg)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

1. Rate of complete expulsion within 24 hr and 48 hr and time to complete expulsion
2. Number of misoprostol doses required; number requiring ERPC
3. Analgesia requirements
4. Infection rate
5. Haemoglobin change/need for blood transfusion
6. Patient satisfaction via questionnaire

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2003

Eligibility

Key inclusion criteria

20-40 patients with diagnosis of missed miscarriages

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

01/04/2003

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Fetal Medicine Unit

London

United Kingdom

E9 6SR

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Homerton University Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration