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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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
02/06/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary
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
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 hypothesis
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

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

Condition
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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2003

Overall study end date
31/12/2003

Eligibility

Participant inclusion criteria
20-40 patients with diagnosis of missed miscarriages

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40

Participant exclusion criteria
Not provided at time of registration

Recruitment start date
01/04/2003

Recruitment end date
31/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Fetal Medicine Unit
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Homerton University Hospital NHS Trust (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