

Oral versus vaginal misoprostol for medical management of early foetal demise

Submission date 26/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/10/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
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
N/A

Study information

Scientific Title

A randomised controlled trial of oral versus vaginal misoprostol for medical management of early foetal demise

Study objectives

When used in conjunction with oral mifepristone (200 mg), a single dose of vaginal misoprostol (800 micrograms) has a higher success rate in treating early foetal demise than an oral regimen of misoprostol (600/400/400 micrograms).

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Tees Hospital Trust Ethics Committee, 23/09/1997, ref: 97/69

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

No participant information sheet available

Health condition(s) or problem(s) studied

Medical management of miscarriage

Interventions

In both groups, oral mifepristone (200 mg) was given and then the misoprostol administered 48 hours later. The vaginal regimen was given once only. If no products were passed/seen, even on vaginal speculum examination, this could be repeated the next day. The oral regime (600/400/400 micrograms) was given at two hourly intervals. Again, if the miscarriage had not completed, this could be reviewed the next day.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mifepristone, misoprostol

Primary outcome measure

Clinically diagnosed completion of miscarriage

Secondary outcome measures

1. Parity, assessed at initial presentation
2. Anembryonic/embryonic early foetal demise assessed at time of ultrasound scan and miscarriage diagnosis
3. Side effects (pain, diarrhoea, vomiting), assessed during treatment and inpatient stay
4. Analgesia use

Overall study start date

01/01/1997

Completion date

30/12/2000

Eligibility**Key inclusion criteria**

Women with an ultrasound diagnosis of (singleton) early foetal demise, with no medical contraindications or known allergy to misoprostol or mifepristone.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

240

Key exclusion criteria

1. Heavy smokers (of >20 cigarettes day)
2. Aged >35 years
3. Severe asthma
4. Cardiovascular disease, hypertension (blood pressure [BP] >160/100 mmHg)
5. Chronic adrenal, renal or hepatic failure
6. Porphyria or haemorrhagic disorders
7. Long term corticosteroid
8. Anticoagulant or non-steroidal anti-inflammatory drug (NSAID) therapy
9. Known allergy to mifepristone or misoprostol

Date of first enrolment

01/01/1997

Date of final enrolment

30/12/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospital of North Tees

Stockton-on-Tees, Cleveland

United Kingdom

TS19 8PE

Sponsor information

Organisation

South Tees Hospitals NHS Trust (UK)

Sponsor details

The James Cook University Hospital

Marton Road

Middlesbrough

England

United Kingdom

TS4 3BW

Sponsor type

Hospital/treatment centre

Website

<http://www.southtees.nhs.uk/live/>

ROR

<https://ror.org/02js17r36>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The James Cook University Hospital (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	01/10/2009	24/10/2019	Yes	No