ISRCTN85124072 https://doi.org/10.1186/ISRCTN85124072

Oral versus vaginal misoprostol for medical management of early foetal demise

Submission date	Recruitment status	[_] Prospectively registered
26/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2019	Pregnancy and Childbirth	

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 mifeprostone (200 mg) was given and then the misoprotol 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