What shall we do with the postdates woman who is not in labour?

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
02/06/2017	Pregnancy and Childbirth	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Kevin Harrington

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0024112467

Study information

Scientific Title

What shall we do with the postdates woman who is not in labour?

Study objectives

Can we reduce the induction to delivery interval and Caesarean section rate in postdates primigravida women undergoing induction of labour with unfavourable cervix?

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

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Induction of labour

Interventions

- 1. Mifepristone
- 2. Standard care

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Mifepristone

Primary outcome measure

- 1. Length of time from induction start (first Prostin) to:
- 1.1. Onset of labour
- 1.2. Second stage
- 1.3. Delivery
- 1.4. Timing and type of intervention (Caesarian Section, Forceps, Ventouse), if any
- 2. Antepartum haemorrhage (APH), postpartum haemorrhage (PPH) and other complications
- 3. Neonatal weight, cord pH and admission to Special Care Baby Unit (SCBU)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2002

Completion date

31/12/2003

Eligibility

Key inclusion criteria

100 pregnant primiparous women who have not laboured at or beyond 41 weeks of gestation with cervival length >3 cm.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/2002

Date of final enrolment

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 (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

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 summaryNot provided at time of registration