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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

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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 summary
Not provided at time of registration