ISRCTN71488751 https://doi.org/10.1186/ISRCTN71488751

A prospective randomised controlled trial of outpatient versus inpatient labour induction with vaginal controlled-release prostaglandin-E2: effectiveness and satisfaction

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
16/10/2014

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr N Mishra

Contact details
Royal Surrey County Hospital NHS Trust
Egerton Road
Guildford
United Kingdom
GU2 7XX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0211184290

Study information

Scientific Title

Study objectives
We hypothesize that the slow release mechanism of vaginal insert would be effective in achieving both cervical ripening and labour onset and patient would be more satisfied remaining at home.

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: Labour induction

Interventions
Inpatient and outpatient groups

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Effectiveness and satisfaction:
1. Effectiveness defined in terms of proportion of women in labour or delivered within 24 hours; requirement for additional intervention e.g. epidural

2. Satisfaction defined as proportion of women with high mean ratings after 12 hours insertion /after delivery

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2006

Completion date
31/07/2007

Eligibility

Key inclusion criteria
1. Primigravida
2. Term
3. Singleton pregnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2006

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Royal Surrey County Hospital NHS Trust
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Royal Surrey County Hospital NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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