

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	☐ Prospectively registered
Registration date 28/09/2007	Overall study status Completed	☐ Protocol
Last Edited 16/10/2014	Condition category Pregnancy and Childbirth	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/2007

Eligibility**Key inclusion criteria**

1. Primigravida
2. Term
3. Singleton pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration