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A randomised controlled trial of the use of the Foley catheter balloon for induction of labour to reduce the incidence of caesarean section in diabetic pregnancies: a prospective clinical, economic and psychological evaluation

Submission date
28/09/2007

Registration date
28/09/2007

Last Edited
28/09/2011

Recruitment status
Stopped

Overall study status
Stopped

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0236180646

Study information

Scientific Title

Study objectives
1. To establish if Foley catheter balloon cervical dilatation can improve the rates of successful induction of labour in insulin-dependent pregnant diabetic women, and thereby reduce caesarean section rates.
2. To establish whether there is an increase in satisfaction with labour and outcome in women who undergo this new method of inducing labour.
3. To establish whether there are any economic advantages to this new method of induction of labour

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
Women consenting to participate in the trial will be randomly allocated to one of two groups:
1. Women will be induced at 38 weeks gestation by means of vaginal prostaglandins according

to our current labour ward protocol.
2. 24 hrs before planned induction of labour, a Foley balloon catheter will be inserted through the cervical canal and inflated to 30ml, and left in situ for 24 hrs, or until it drops out when the cervix has dilated to 4cm+, which ever occurs earlier. Labour is then induced as per protocol used in women in group 1.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Vaginal delivery versus caesarean section.
1. Clinical: induction success rates, caesarean section rates, length of labour, instrumental delivery, blood loss and neonatal outcomes including Apgar scores, admission to SCBU and blood glucose levels.
2. Psychological: maternal satisfaction rates assessed by a designer questionnaire.
3. Economic: basic costs assessment, including the costs of Foley catheters, additional 24 hour hospital stay, costs of caesarean section etc.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

Completion date
01/05/2006

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40 women should be recruited to each group - 80 women in total.

Key exclusion criteria
Women will be excluded if they are planning an elective caesarean delivery, are multiparae, have co-existing other medical disorders, multiple pregnancy, breech or any presentation other than cephalic.

Date of first enrolment
01/11/2003

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Obstetrics Dept
London
United Kingdom
SW17 0QT

Sponsor information

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
St George's Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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