

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	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/09/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

London

United Kingdom

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+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

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