

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	☐ Prospectively registered
		☐ Protocol
Registration date 28/09/2007	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 28/09/2011	Condition category Pregnancy and Childbirth	☐ 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
Mr Isaac Tainzana Manyonda

Contact details
Obstetrics Dept
Lanesborough Wing
St George's Hospital
Blackshaw Road, Tooting
London
United Kingdom
SW17 0QT
+44 020 8725 3771
i.manyonda@sghms.ac.uk

Additional identifiers

Protocol serial number
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

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

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Obstetrics Dept

London

United Kingdom

SW17 0QT

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

St George's Healthcare NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration