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A randomised controlled trial of two decision aids for mode of delivery among women with a previous caesarean section

Submission date
21/07/2004

Recruitment status
No longer recruiting

Registration date
07/09/2004

Overall study status
Completed

Last Edited
10/02/2010

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

Study information

Scientific Title

Acronym
The DiAMOND trial (Decision Aids for Mode Of Next Delivery)

Study objectives
Women who have experienced a previous caesarean section are faced with a difficult decision between repeat elective caesarean section and trial of vaginal delivery in subsequent pregnancies. The aim of this study is to investigate two different methods of assisting pregnant women reach a decision about mode of delivery.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy, with one previous caesarean section

Interventions
1. Decision analysis
This firstly requires elicitation of utilities (preference values) from women regarding the possible outcomes of both planned vaginal delivery and repeat elective caesarean section. Utilities will be measured via a computerised interview. These utilities will then be combined

with probabilities of each outcome in a decision analysis tree. Each woman will be given a computer printout of the outcome of the decision analysis, a recommended 'preferred option' based on maximised expected utility.

2. Interactive information programme
This is an innovative way of providing information about the outcomes and associated risks and benefits involved in the decision. Unlike a videotape or written information, the programme will allow women to more easily tailor the information they view, and sections can be interrupted or repeated as required. The sections viewed are recorded. In addition, women in this group will be given a password that will allow them to access the information programme via the internet as often as they wish. An important difference from the decision analysis intervention is that women¿s preferences are not explicitly sought and there is no recommendation of a 'preferred option' for the individual.

3. Usual care
This will comprise standard care given by the obstetric and midwifery team. Women allocated to decision analysis or information programme will receive these interventions in addition to usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Actual mode of delivery
2. Decisional Conflict at 37 weeks gestation

Secondary outcome measures
1. Anxiety
2. Knowledge
3. Perception of shared decision making
4. Satisfaction with decision making process
5. Proportion of women attempting vaginal delivery

Overall study start date
01/05/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Pregnant women with one previous lower segment caesarean section, no current obstetric problems and delivery expected at ≥37 weeks. Recruitment will take place during the initial booking visit at approximately 12-14 weeks' gestation. Participating centres are maternity units at St Michaels and Southmead Hospitals in Bristol, and Ninewells Hospital in Dundee.

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
660

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Primary Health Care
Bristol
United Kingdom
BS6 6JL

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Senate House
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Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

Website
http://www.bristol.ac.uk

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
The BUPA Foundation (UK) (ref 657/G10)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protcol	10/12/2004		Yes	No
Results article	results	23/06/2007		Yes	No
Other publications	economic evaluation	01/07/2010		Yes	No