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A study of position during the late stages of labour in women with an epidural

Submission date
19/08/2009

Recruitment status
No longer recruiting

Registration date
26/08/2009

Overall study status
Completed

Last Edited
18/05/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Epidurals are the most effective method of relieving pain during labour. About 150,000 women have epidurals during childbirth in the UK each year and they consistently report high levels of satisfaction. However, epidurals do have some disadvantages. Studies have shown that they increase the chance of women needing help to delivery their baby using forceps or vacuum suction. During an instrumental delivery a woman may need to have an episiotomy or my find it causes a tear in her birth canal as her baby is born. Instrumental deliveries also increase the risk of subsequently developing loss of bowel control (incontinence), leaking urine and suffering sexual problems after childbirth. There is debate about whether adopting an upright position during the late stage of labour, when the neck of the womb is fully open, gives a greater chance of having a normal vaginal birth. It is thought that an upright position may help by several different mechanisms: gravity may help align the baby more correctly in the birth canal and may increase the blood supply to the womb; it may also result in stronger contractions of the womb and assist a woman to push more effectively at delivery. At present few women who have an epidural are encouraged to be upright in the late stage of labour. Most adopt a position lying down or half-sitting in bed. However, advances in epidural pain relief over the last two decades have resulted in the widespread use of a technique that allows women to move around rather than to be immobile. This approach uses low doses of local anaesthetic, the drug which was responsible for leg weakness in old-style epidurals, together with another painkiller called fentanyl. With these 'mobile' epidurals, most women are able to move around safely whilst in labour, including the late stages of labour, and remain comfortable. Furthermore, the chance of needing an instrumental delivery is much less, although still greater than with no epidural. The aim of this study is to find out whether adopting an upright position throughout the second stage of labour decreases the need for instrumental vaginal delivery, compared with adopting a 'lying-down' position.

Who can participate?
Women who are in labour for the first time and who have an effective epidural, and for whom no complications are expected

What does the study involve?
Participating mothers are randomly allocated to one of two groups: one group is encouraged by

the midwife to adopt as upright a posture as possible (this would include walking, standing, sitting out of bed or sitting bolt upright in bed) for as much as possible of the late stage of labour, right up to their baby's birth, and the other group are asked to adopt a lying down position in bed. The health of participating mothers and babies are measured up to 1 year after birth with a postal or telephone questionnaire.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
April 2010 to April 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof Peter Brocklehurst
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Contact information

Type(s)
Scientific

Contact name
Prof Peter Brocklehurst

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
A study of position during the late stages of labour in women with an epidural: a randomised controlled trial

Acronym
BUMPES

Study objectives
In nulliparous women who chose mobile epidural anaesthesia, does a policy of adopting an 'upright position' throughout the second stage of labour cause an increase in the incidence of spontaneous vaginal delivery (SVD) compared with a policy of adopting a 'lying-down' position.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted before the end of September 2009

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Labour/birthing position

Interventions
1. Women allocated to an 'upright position' would aim to be in positions where their pelvis is in as vertical a plane as possible during the second stage of labour.
2. Women allocated to a 'lying-down position' would aim to be in positions where their pelvis is in as horizontal a plane as possible during the second stage of labour.

Intervention Type
Behavioural

Primary outcome measure
Incidence of spontaneous vaginal delivery (SVD)

Secondary outcome measures
1. Mode of delivery
2. Outcomes from randomisation until delivery
3. Immediate post delivery outcomes
4. Postnatal period for both mother and infant
5. 1-year outcomes for both mother and infant

Overall study start date
01/04/2010

Completion date
30/04/2015

Eligibility

Key inclusion criteria
Women who are:
1. Nulliparous
2. Single cephalic presentation
3. Greater than or equal to 37 weeks gestation
4. Intend spontaneous vaginal birth
5. In second stage of labour
6. With an effective mobile epidural in situ

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3,000

Key exclusion criteria
Unable to understand written and spoken English language

Date of first enrolment
01/04/2010

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
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Headley Way
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England
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OX3 9DZ
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Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/rso/clinical/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/11/2016

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?
Results article	results	18/10/2017		Yes	No