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Study of correlation between the extent of spread of cerebro-spinal fluid measured using Magnetic Resonance Imaging and the severity of headache following accidental dural puncture during epidural catheter placement for labour analgesia

Submission date
18/12/2017

Recruitment status
No longer recruiting

Registration date
08/01/2018

Overall study status
Completed

Last Edited
22/01/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims

In the UK 1 in 3 women choose an epidural for pain relief during childbirth, as it remains the most effective choice. Pain sensation is conveyed to the brain via nerves that are connected through the spinal cord, which floats in a bag of fluid (dural sac) further protected inside a hollow bony column (vertebral column). The dural sac contains fluid (cerebrospinal fluid or CSF), and its coverings are made of three layers of membranes (dura mater, arachnoid mater and pia mater). The spinal cord is connected directly with the brain, and the dural sac and covering membranes continue upwards in the skull to enclose the brain. Epidural involves placement of a plastic tube by an anaesthetic doctor, through a needle, into a space that lies between the outermost membrane of the sac and the wall of the bony canal (epidural space). In an uncomplicated procedure, this placement of the plastic tube is achieved without puncturing the membranes. However, in 1% cases, the dura may get punctured by the needle leading to the leakage of spinal fluid. It is believed that such a leakage causes traction on the membranes producing headache in 80% of women (called postdural puncture headache or PDPH). If severe this may require an invasive procedure (called an epidural blood patch or EBP) for effective treatment. PDPH can be very incapacitating and debilitating for the new mother; restricting daily activities, impairs looking after her baby, impedes mother-baby bonding and can delay discharge from hospital. In simple terms, PDPH can turn an enjoyable experience into an unpleasant one, with substantial physical, emotional and psychological consequences. Currently, there is no scientific investigative tool that can predict the development, progress and severity of PDPH. Current management relies on a “wait and watch” strategy. This has serious limitations, including unnecessary suffering for the new mother by delayed diagnosis, potentially delayed definitive treatment (EBP), and premature discharge with subsequent readmission. Magnetic resonance imaging (MRI) is a routine investigation tool, frequently used in other fields of

medicines (neurology, neurosurgery etc), that can provide high resolution images of spinal cord, its surrounding membranes, spinal fluid and its leakage into the epidural space. This study will be the first attempt to scientifically evaluate the link between features identified on MRI images taken soon after accidental puncture of the dura, and the development, progress and severity of ensuing headache. This may help clinicians to reliably identify the patients at risk of developing more severe headache and offer early institution of effective treatment (EBP), on the basis of scientific evidence instead of the current “wait, watch and intervene” strategy. The aim of this study is to help reduce unnecessary suffering for the new mother and minimise the disruption to family life due to PDPH.

Who can participate?
Adult woman aged 16 and older in labour who received an epidural/CSE for pain relief and sustained an observed ADP with an epidural needle.

What does the study involve?
After recognition of an accidental dural puncture the participant is managed according to the local protocols. Once the baby is delivered and both the mother and the newborn are in reasonably good health, the mother are approached by a member of the direct care team, who explores her potential participation in the study. The local investigator liaises with the local radiology department to arrange an MRI scan as soon as possible, but no later than 24 hours from the detection of ADP. The local investigator accompanies the mother to the MRI scanner. Once the MRI scan is done the mother continues to be managed according to the local protocols. The direct care team are not informed about the MRI scan findings. All the participating women are followed up for the development of PDPH daily for 1 week in person or over the telephone. A follow-up questionnaire is used by the local investigators (LI) for data collection and follow up.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

Where is the study run from?
This study is being run by University College London Hospitals NHS Foundation Trust (UK) and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
January 2012 to March 2018

Who is funding the study?
National Institute of Academic Anaesthesia (UK)

Who is the main contact?
Dr Amer Majeed

Contact information

Type(s)
Scientific

Contact name
Dr Amer Majeed

ORCID ID

http://orcid.org/0000-0003-2255-6950

Contact details
Consultant Anesthesiologist
King Faisal Specialist Hospital and Research Centre
Riyadh
Saudi Arabia
11211

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14310

Study information

Scientific Title
Does Magnetic Resonance Imaging (MRI) correlate with severity of headache following accidental dural puncture (ADP) during epidural catheter placement for labour analgesia?

Acronym
MRiADP

Study objectives
There is a positive correlation between the extent of spread of cerebro-spinal fluid measured using Magnetic Resonance Imaging and the severity of headache following accidental dural puncture during epidural catheter placement for labour analgesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research and Ethics Service Committee North West - REC, 23/07/2012, ref: 12/NW/0528

Study design
Interventional; Design type: Diagnosis, Imaging

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and Sexual Medicine; UKCRC code/ Disease: Reproductive Health and Childbirth/ Complications of labour and delivery

Interventions
Participants receiving epidurals for labour analgesia, who sustain an accidental dural puncture (ADP), would undergo clinical management according to the local departmental protocols as usual. If they agree to participate in this study, they would undergo Magnetic Resonance Imaging (MRI) of their brain and lumbar spine, without contrast, within 48 hours from the occurrence of the ADP. They are also followed up for one week for development of symptoms associated with Post Dural Puncture Headache (PDPH). The images and follow up data are psudoanonymised. These are then reported and analysed by the study neuro-radiologist and the study coordinator respectively.

Intervention Type
Other

Primary outcome measure
Presence, or otherwise, of a statistically significant positive correlation between the extent of spread of cerebro-spinal fluid measured using Magnetic Resonance Imaging and the severity of PDPH according to a carefully designed scoring system developed by the study team.

Secondary outcome measures
Incidental findings on the images measured using Magnetic Resonance Imaging.

Overall study start date
01/01/2012

Completion date
31/03/2018

Eligibility

Key inclusion criteria
All adult (>16 years of age) women in labour who received an epidural / CSE for pain relief and sustained an observed ADP with an epidural needle.

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
Planned Sample Size: 31; UK Sample Size: 31

Total final enrolment
30

Key exclusion criteria
1. Patient refusal
2. Unsuitable for MRI (e.g. metal implants, pace maker etc)
3. Pre-existing headaches / migraine, spinal surgery
4. Spine deformity or anomalies

Date of first enrolment
01/09/2013

Date of final enrolment
08/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals NHSFT
London
United Kingdom
NW1 2BU

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre

St Mary's Hospital
Manchester
United Kingdom
M13 9WL

Study participating centre
Kings College Hospital NHSFT
London
United Kingdom
SE5 9RS

Study participating centre
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
Royal Berkshire NHSFT
Reading
United Kingdom
RG1 5AN

Study participating centre
University Hospitals Coventry and Warwickshire NHST
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

Sponsor details
250 Euston Road
London

England
United Kingdom
NW1 2PG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Government

Funder Name
National Institute of Academic Anaesthesia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V5.1	22/06/2015	08/01/2018	No	Yes
Protocol file	version V8.1	12/06/2016	08/01/2018	No	No
Results article	results	01/01/2021	22/01/2021	Yes	No