Protocol

(Version: 8.1, Dated: 12/06/2016)

Chief Investigator:
Dr Roshan Fernando

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

A multicentre study by the MRiADP group

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Background:

Approximately 1% of epidurals placed for labour analgesia are complicated with Accidental Dural Puncture (ADP) in the UK [1]. Post Dural Puncture Headache (PDPH) is a debilitating complication which may follow ADP in 70-80% of cases [2,3]. The PDPH frequently interferes with the daily activities of the mother and can disrupt maternal-infant interaction. Moreover, an untreated PDPH may result in rare but serious morbidity and mortality [4,5]. It is a significant cause of increased anaesthetic workload and prolonged hospital stay [6]. It is the third most common reason for litigation in obstetric anaesthesia [7]. Epidural blood patch (EBP) is the most effective treatment for PDPH, but the procedure itself is associated with complications, including the risk of another ADP and worsening of headache [8]. The onset of a PDPH following an ADP is difficult to predict, hence EBP is often delayed until the development of severe/debilitating PDPH when the benefits of EBP outweigh potential risks. It may, therefore, be of value in identifying those women most likely to develop a PDPH.

Magnetic Resonance Imaging (MRI) can identify several important markers, and an attempt can be made to investigate the link between these and development / severity of PDPH:

- the presence and extent of CSF in the epidural space following ADP (widely believed to be the cause of PDPH in the light of indirect evidence like intracranial hypotension, but has not been proven directly yet) [9].
- blood in the epidural space (possibly responsible for less headache) or intrathecally (potentially causing headache in its own right and / or plugging off the dural hole causing reduction in CSF leak) [9].
- Dural shift in epidural space associated with fluid / blood in the same space (may demonstrate tamponade effect, and potential reduction of headache)
- Meningeal enhancement and downward displacement of the brain (widely accepted surrogate for loss of CSF contributing to PDPH) [10].

Literature search:

There is no published study which has investigated the association of PDPH following ADP with MRI demonstrable CSF leak or blood into the epidural space, or sagging of brain.

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

Objectives:

This study will aim to investigate on MRI scan the extent of CSF leak in the epidural space following ADP, and evaluate if there is an association with the development and severity of PDPH. Additional markers like blood in epidural space, dural shift / compression, and sagging of brain will also be studied for similar associations.

Scope of the Study:

In current practice whether a patient receives an EBP as a therapeutic intervention for PDPH depends on the severity of the PDPH, and EBP is generally delayed until the benefits of EBP

MRiADP Study

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

outweigh risks. Such a practice requires continual observation of the patients for several days and often patients may be discharged home headache-free but later on develop a headache. Currently, there is no scientific evidence which enables us to predict which patients are at risk of developing severe PDPH necessitating EBP. This study will serve as a pilot to discover, or not the least importantly rule out, an association between development / severity of PDPH and the presence of MRI demonstrable / gradable CSF collection in the epidural space ("wet" spine scenario).

The possible outcome scenarios and their perceived implications on clinical practice will be as follows:

- If such a relationship is found, this could assist us in the early identification of parturients who are at risk of severe PDPH and would allow an informed discussion and offer of possible early intervention before severe headache ensues, thus potentially improving patient experience, and reducing its associated morbidity / mortality, as well as management costs.

  We know that 70-80% of these women will go on to develop PDPH, therefore this would not only benefit the patient, but would have great cost-saving implications, as would result in reduced length of stay for these patients, who are usually managed on an in-patient basis.

- If the degree of CSF leak is not linked with the severity of PDPH, it may be possible to find an association with other MRI markers responsible for this effect e.g. presence of intrathecal / epidural blood, presence of dural shift (tamponade effect from fluid / blood in epidural space), or sagging of brain (degree of intracranial hypotension). In such
- If, however, no association is found i.e. PDPH developing despite absence of CSF leak ("dry" spine scenario), depending on the statistical strength of the findings it may imply the need for larger studies, or the futility and risk of offering EBP to these patients (the original doctrine of CSF leak producing PDPH may become invalidated). It may also help us understand why some patients do not benefit from EBP or only get a temporary effect.

Research Group:

Acronym for the study: MRiADP study.

- Lead Investigator (LI): Dr Roshan Fernando, Consultant Anaesthetist, London
- Participating Hospitals with designated Principal Investigators (PIs):
  - Buckinghamshire Healthcare NHST
  - Central Manchester University Hospitals NHSFT
  - Hull and East Yorkshire Hospitals NHST
  - Kings College Hospital NHSFT
  - Lancashire Teaching Hospitals NHSFT
  - Norfolk and Norwich University Hospitals NHSFT
  - Royal Berkshire NHSFT
  - St Helens and Knowsley Hospitals NHST
  - University College London Hospitals NHSFT
  - University Hospitals Coventry and Warwickshire NHST

- Radiology reporting: arranged by University College London Hospitals NHSFT
- Statistical analysis: Dr Malachy Columb, Consultant Anaesthetist, University Hospital South Manchester, Manchester
- Research Co-ordinator (RC): Dr Amer Majeed, Consultant Anaesthetist

Chief Investigator:
Dr Roshan Fernando

Study Period: 4 years. September 2013 – August 2017

Materials and Methods:

After ethics approval from the NREC, and local R&Ds, the study will be conducted simultaneously in all participating hospitals. Local purchasing contracts will be sought with radiology departments of participating hospitals.

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

- Study design: Prospective, double-blind, quasi-observational study
- Sample size: Pearson R correlation method calculates that a sample size of 24 will be required to find a correlation of at least 0.6 or better with > 90% confidence interval ($p < 0.05$). To compensate for possible drop outs, we determine to recruit 35 patients in our study.
- 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.
- Exclusion criteria: patient refusal, unsuitable for MRI (e.g. metal implants, cochlear implants, intra-cranial clipping), pre-existing headaches / migraine, spinal surgery, spine deformity or anomalies, claustrophobia. Epidural / spinal catheter planned to be retained during MRI.
- Recruitment: Upon recognition of ADP the parturient will be offered the information sheet describing the study followed by discussion with the local Principal Investigator (PI). Written informed consent will be obtained on a prescribed form. It will be retained in the patient's case notes.
- Coding Protocol: All participating women will be codified locally i.e. they will be allocated a study number by the PI, comprising of three letters relating to the hospital name, and a three digit serial number issued sequentially (e.g. UCL-001). This code, but no other patient identifiers, will be divulged for any information or images shared with the study group. The details of a code will only be known to the local PI, and will be retained for one year after the end of study period. The participant will be excluded from the study if the code will need to be broken for any reason e.g. treating physician's / patient's request, or incidental finding of serious pathology on MRI needing further investigation or treatment (e.g. space occupying lesions).
- Conduct of study:
  - Participants will undergo, T1 & T2 weighted sagittal MRI scans of the lumbar spine and head without contrast, between 12 – 48 hours following ADP, but after delivery and removal of any epidural / intrathecal catheters.
  - In order to ensure blinding, the radiology department will replace the patient particulars on the MRI scan for each participating women with a code provided by the local PI. Images will not be reported locally, instead those will be codified and copied on a CD, and sent by recorded delivery, to the radiologist members of the study group. They will be reporting those on voluntary / unpaid basis. The local radiology departments will invoice the Chief Investigator, for the cost of the scan excluding the reporting fee, on a case to case basis at an already agreed rate.
  - Study Radiologists will be blinded to the parturient's clinical details as they will only receive coded scan images. They will report the MRI scan according to a defined format (Appendix A), and send the report to the research coordinator. As the report will be based on an already coded scan, no further anonymisation will be required.

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

- A standardised form (Appendix B) will be used by PIs for data collection and daily follow up for one week in person or over the phone. Completed codified forms will be sent to the research coordinator.
- Except for MRI, all women with an ADP will be managed according to the local clinical protocol.
- All participating women with an ADP will be followed up for the development of PDPH daily for 1 week: in person (if in-patient) or over the telephone (if discharged).

Results analysis:

Because not all women who experienced ADP develop PDPH, therefore, following completion of follow-up participating women will be assigned into PDPH and non-PDPH groups. MRI findings will be compared between two groups.

- Primary outcome: to ascertain MRI findings, that is only observed in participants with PDPH.
- Secondary outcome: to correlate MRI findings with severity of PDPH.

Appendix C outlines the scoring system to classify severity of PDPH. Appendix D grades MRI findings that could be identified in patients with PDPH. Appendix E describes correlation between grades of MRI findings and severity of PDPH.

Hypothesis:

Severity of headache, following ADP, directly correlates with the extent of spread of CSF leaked in the epidural space in the vertical and other dimensions (posterior / lateral / anterior).

Note: Secondary findings (blood in epidural space, dural shift etc) will be used in a secondary analysis for example: correlation with blood in epidural space + CSF leak and incidence of headache – same / higher or lower, dural shift + CSF leak and incidence of headache – same / higher or lower, etc.

Funding:

A research grant has been approved by the National Institute of Academic Anaesthesia (Ref number WKR0-2012-0028), for a sum of £15,000 to cover the cost of MRI scans for 32 patients.

Ethics approval:

The study has been approved by the NRES North West - Greater Manchester North (Reference number 12/NW/0528).

MRI ADP Study

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

References:

1. NHS Maternity Statistics, England - 2009/10. Department of Health, London 2010.
2. Chan T.M.L., Ahmed E., Yentis S. M., Holdcroftc A. Postpartum headaches: summary report of the National Obstetric Anaesthetic Database (NOAD) 1999. Int J ObsAnesth. 2003;12:107–112
3. Paech M, Banks S, Gurrin L. An audit of accidental dural puncture during epidural insertion of a Tuohy needle in obstetric patients. Int J ObstetAnesth 2001; 10: 162–7.
4. Evans R. Complications of lumbar puncture. NeurolClin 1998; 16:83–105.
5. Reynolds F. Dural puncture and headache. BMJ 1993; 306: 874–6.
6. Van de Velde M., Schepers R., Berends N., Vandermeersch E., De Buck F. Ten years of experience with accidental dural puncture post-dural puncture headache in a tertiary obstetric anaesthesia department. INT J OBS ANESTH. 2009;17:329–335
7. Chadwick HS. An analysis of obstetric anesthesia cases from the American Society of Anesthesiologists' closed claims project database. Int J ObstetAnesth 1996,5:258-63
8. Sudlow C, Warlow C. Epidural blood patching for preventing and treating post-dural puncture headache. Cochrane Database, Syst Rev.2002;(2):CD001791
9. Vakharia SB et al. Magnetic Resonance Imaging of Cerebrospinal Fluid leak and Tamponade Effect of Blood Patch in Postdural Puncture Headache. AnesthAnalg. 1997;84:585-90
10. Chen-San Su, Min-Yu Lan, Yung-Yee Chang, Wei-Che Lin, Kuan-Ting Liu. Clinical Features, Neuroimaging and Treatment of Spontaneous Intracranial Hypotension and Magnetic Resonance Imaging Evidence of Blind Epidural Blood Patch. EurNeurol 2009;61:301–307

MR ADP Study

PROFORMA FOR DATA COLLECTION

APPENDIX A

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

1 Patient details:

- Code Number: XXX-001 (hospital initials + patient sequence number)
- Height
- Weight or BMI at Labour: _____ at booking: _____

2 Labour details:

- Gestation: _____ wks
- Onset of labour: Spontaneous / induced / augmented
- Mode of delivery: SVD / Instrumental / LSCS
- Time of delivery ___ : ___ Hrs Date of delivery ___ / ___ / ___

3 Epidural details:

- Tuohy Needle Size: 16G / 18G / other _____
- Position of patient Sitting / Lateral
- Lumber Inter-space: L4-5 / L3-4 / L2-3 / L1-2
- Bloody Tap: Yes / No (Blood seen coming through needle, catheter, or CSF)
- Multiple attempts: Yes / No (Reposition of needle after hitting the bone = one attempt)
- Number of ADPs 1 / 2 / 3 or more

4 PDPH (severe, dull, non-throbbing pain, usually fronto-occipital, aggravated in the upright position and diminished in the supine position)

- Onset of headache
  - ADP to headache time _____ hours
  - Headache first developed after discharged home Yes / No
- EBP: Yes / No Volume of injected blood _____ mls
- ADP to EBP time (Days) _____
- Effect of EBP PDPH resolved / Repeat EBP done
- Effect of repeat EBP PDPH resolved / further repeat EBP done

5 Prophylaxis / treatment of PDPH:

- Any prophylactic treatment BEFORE MRI
  - Epidural fluid bolus / infusion quantity?
  - Spinal catheter Yes / No
  - Duration of spinal catheter from insertion (up to the time of MRI) _____ hours
  - Fluid via spinal catheter Yes / No
  - Other _____

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

- Any prophylactic treatment AFTER MRI (in addition to Paracetamol, NSAIDs and Opioids)
  - Caffeine
  - Sumatriptan
  - Other (please describe) _____
- Any other treatment of PDPHParacetamol / NSAIDs / Opioids / Caffiene / Sumatriptan / Other (please write details below)

  _____

6 Post ADP Follow up: (please tick appropriate boxes for presence of PDPH, encircle other symptoms)

* Associated symptoms: visual disturbances (V) – photophobia, double vision, floaters

auditory disturbances (A) – tinnitus, muffled sounds

nausea / vomiting (N),

** Severity of headache Mild headache = coping without opioidsModerate headache = coping with opioidsSevere headache = limiting activities of daily living

Headache	None	Mild	Moderate	Severe	Other symptoms
Day 0					V / A / N
Day 1					V / A / N
Day 2					V / A / N
Day 3					V / A / N
Day 4					V / A / N
Day 5					V / A / N
Day 6					V / A / N
Day 7					V / A / N

Additional Information / comments (if any):

PROFORMA FOR MRI REPORT APPENDIX B

Patient Code Number: XXX-001 (hospital initials + patient sequence number)

Lumbar Spine MRI

1 CSF spread

- Vertebral levels
- Lateral … right / left
- Posterior
- Anterior
- Circumferential

2 Blood … Intrathecal / extradural

3 Dural shift >2mm

Brain MRI

1 Meningeal enhancement

2 Downward displacement of the brain

Additional Information / comments (if any):

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

MRI ADP Study

GRADING SYSTEM FOR SEVERITY OF HEADACHE

Appendix C

- Headache will be assessed on four point Visual Analogue Scale (VAS) i.e. None, Mild, Moderate and Severe.

Grade	Characteristics
I	No headache
II	Mild headache as described by patient on VAS scale treated with < 2 analgesics of the following; Paracetamol (PO/IV), NSAIDS, Tramadol, mild opioids (codeine, dihydrocodeineetc) *Plus all of the below;* No delay in discharge due to headache No interference with activities of daily living (ADLs); standing up, walking, bath, toilet No interference with looking after the baby; breast feeding, nappy change
III	Mild or Moderate headache as described by patient on VAS scale treated with < 2 analgesics of the following; Paracetamol (PO/IV), NSAIDS, Tramadol, mild opioids (codeine, dihydrocodeineetc) *Plus any of the below:* Delay in discharge due to headache Some interference with ADLs; standing up, walking, bath, toilet Some interference with looking after the baby; breast feeding, nappy change
IV	Moderate headache as described by patient on VAS scale treated with >2 analgesics of the following; Paracetamol (PO/IV), NSAIDS, Tramadol, mild opioids (codeine, dihydrocodeineetc) *Plus all of the below:* Delay in discharge due to headache Some interference with ADLs; standing up, walking, bath, toilet Some interference with looking after the baby; breast feeding, nappy change
V	Severe headache as described by patient on VAS scale treated with >2 analgesics of the following; Paracetamol (PO/IV), NSAIDS, Tramadol, mild opioids (codeine, dihydrocodeineetc) and strong opioids (Morphine etc) *Plus any of the below:* Treatment with strong opioids (Morphine etc) Delay in discharge due to headache Significant interference with ADLs; standing up, walking, bath, toilet Significant interference with looking after the baby; breast feeding, nappy change

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST
Central Manchester University Hospitals NHSFT
Hull and East Yorkshire Hospitals NHST
Kings College Hospital NHSFT
Lancashire Teaching Hospitals NHSFT
Norfolk and Norwich University Hospitals NHSFT
Royal Berkshire NHSFT
St Helens and Knowsley Hospitals NHST
University College London Hospitals NHSFT
University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

VI	Severe headache as described by patient on VAS scale treated with >2 analgesics of the following; Paracetamol (PO/IV), NSAIDS, Tramadol, mild opioids (codeine, dihydrocodeineetc) and strong opioids (Morphine etc) *Plus all of the below:* Delay in discharge due to headache Significant interference with ADLs; standing up, walking, bath, toilet Significant interference with looking after the baby; breast feeding, nappy change

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

MRI ADP Study

Grading of MRI Scan characteristics: Appendix D

CSF spread within epidural space following ADP will be examined in a MRI scan image. Extent of spread into posterior section of epidural space will be measure first followed by identification of lateral and anterior spread.

Grades	Characteristics
I	No CSF spread in epidural space
II	<2 vertebral levels *plus* Lateral spread
III	As above *plus* Anterior spread
IV	2-4 vertebral levels *plus* Lateral spread
V	As above *plus* Anterior spread
VI	>4 vertebral levels *Plus any of the below;* Lateral spread Anterior spread

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST
Central Manchester University Hospitals NHSFT
Hull and East Yorkshire Hospitals NHST
Kings College Hospital NHSFT
Lancashire Teaching Hospitals NHSFT
Norfolk and Norwich University Hospitals NHSFT
Royal Berkshire NHSFT
St Helens and Knowsley Hospitals NHST
University College London Hospitals NHSFT
University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

Example of Correlation between grades of MRI findings and severity of PDPH: Appendix E

MRI scan Characteristics	Predictability of headache
Grade I changes	No headache
Grade II changes	10% risk of mild to moderate headache
Grade III changes	25% risk of mild to moderate headache
Grade IV changes	50% risk of moderate to severe headache
Grade V changes	75% risk of moderate to severe headache
Grade VI changes	75% risk of severe headache

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

MRI ADP Study

Chief Investigator:
Dr Roshan Fernando

Recruitment sites:
Buckinghamshire Healthcare NHST

Central Manchester University Hospitals NHSFT

Hull and East Yorkshire Hospitals NHST

Kings College Hospital NHSFT

Lancashire Teaching Hospitals NHSFT

Norfolk and Norwich University Hospitals NHSFT

Royal Berkshire NHSFT

St Helens and Knowsley Hospitals NHST

University College London Hospitals NHSFT

University Hospitals Coventry and Warwickshire NHST

Enquiries:
Dr Amer Majeed
amer.majeed@doctors.org.uk
Tel: 01618832829

Suggested steps for recruitment: Appendix E

1. Trigger – Accidental Dural Puncture (ADP), with tuohy needle, witnessed during labour epidural placement.
2. Clinical management of the patient according to departmental protocols: no need to alter anything for this study.
3. Potentially suitable for recruitment if ADP occurs between Sunday afternoon to Friday morning. Notify Dr _____ (PI) or duty anaesthetic consultant of the day for initiating preparations.
4. It might be helpful to brief the midwife in attendance of that patient / midwife in charge for the shift as well.
5. Potential MRI slot to be identified, between 12-48 hours from the time of ADP, in consultation with Chief MRI Technician (name) or anyone else on duty at (telephone). Out of hours, radiology registrar on call to be contacted, for passing on the message to MRI scan reception in the morning, to identify a potential slot.
6. After delivery, when the patient had a chance to become comfortable and refreshed, a member of anaesthetic staff with current GCP certificate, to approach the patient for the study. Verbal explanation and patient information leaflet to be given. If she would need some time to think about it, she should be visited again when appropriate, and consent form completed in triplicate.
7. Completed consent form copies should be retained in the patient hospital records, in the study site file, and a copy given to the patient.
8. MRI scan to be booked on hospital systems (Head & Lumbar spine, without contrast), and request confirmed to MRI scan reception over the phone.
9. Appropriate childcare arrangements to be discussed with the family/midwife for the duration of the scan (30-40 minutes approximately).
10. Patient may be accompanied to the scan by the midwife or a doctor depending on the clinical requirements.
11. The scan will not be reported locally, and treating clinicians will not be permitted to retrieve / view the scan (to avoid treatment bias). The images will be codified and sent to the Chief Investigator, Dr Roshan Fernando, at the following address for reporting by the study radiologist:

    Dr Roshan Fernando
    Consultant Anaesthetist
    Department of Anaesthetics
    3rd floor Maple Link Corridor
    UCLH
    235 Euston Road
    London NW1 2BU
12. The patient will be followed up for seven consecutive days, in person if inpatient or over the phone if already discharged home. A simple proforma to be updated daily during the week.
13. Completed proforma to be returned to the study site file, and a scanned copy to be sent to Dr Amer Majeed (Study Coordinator), at amer.majeed@doctors.org.uk.