# Patient Information Sheet

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NRES North West, Greater Manchester North approval number 12/NW/0528


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

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University Hospitals Coventry and Warwickshire NHST



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


## Study title

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

## Invitation paragraph

*We would like to invite you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.*

## What is the purpose of the study?

This study will aim to use scanning of your head and spine (MRI or magnetic resonance imaging), to discover a link if any, between the severity of the headache that many patients experience, and the degree of fluid leakage in your spine, after the accidental puncture of the lining of the protective bag of fluid containing your spinal cord and the nerves (Accidental dural Puncture, or ADP in short).

## Why have I been invited?

You have unfortunately had a complication of epidural injection called ADP, as described above. After ADP, about 80% of the patients go on to develop a very bad headache, called Post Dural Puncture Headache or PDPH in short. Although simple treatments like oral pain killers, and drinking plenty of water, helps to cure PDPH in about two thirds of the patient, yet remaining one thirds need another epidural injection to perform a blood patch (called Epidural Blood Patch, or EBP in short) around the site of the leakage. Currently there are no scientific means available to identify those patients who could be at risk of developing a more severe headache, who might therefore benefit from an early offer of EBP. You can help the medical profession, and the future patients, by agreeing to participate in this research attempting to find that missing link.

## Do I have to take part?

*No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will ask you to sign a*

MRI ADP Study

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*consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.*

**What will happen to me if I take part?**

- You will be part of this study for only the first week after your ADP. It will not alter in any way the treatment and care that you would have otherwise received, nor will it require you to stay in the hospital for any longer than ordinarily required for your treatment. Once you will have gone home, we shall follow you up over the phone but not beyond the first week as explained above.
- ***Within the first 48*** hours after the ADP an MRI scan will be arranged. You will be taken to the radiology department for your scan, which will last for about half an hour. You will not require any additional medicine for the scan. You will be transferred back to the ward after the scan.
- A member of the research team will follow you up for one week following the scan, on daily basis, to record your progress. He / she will ask you a few questions and complete a questionnaire every time. This will take approximately 5 minutes on each occasion. This will not delay your discharge from the hospital. After you had gone home, a member of the research team will contact you daily on the phone, to ask the same questions, to complete the follow up during the first week.
- The member of the research team completing this form may need to look at the relevant sections of your medical records and transcribe necessary information, such as the medicines given to you and their dosages, onto the study forms.
- From the research point of view, you will not be required to attend any extra clinics or see the doctors. However, you will be free to seek medical help, or contact us, should you desire for any reasons.
- Your personal details will not be available to anyone outside this hospital. Your scan images will remain on the hospital computers like your other medical records. These will not be reviewed by the doctors in this hospital. Instead, a copy of the images will be sent to an expert after replacing your name and other details with a code. The details of the code will not be known to anyone except the research team member in our hospital, not even to rest of the research team. This will be done to protect your privacy and anonymity.
- Your follow up data from the questionnaires will be codified and anonymised in a similar way. The coded scan results, and questionnaire data will be sent to the research coordinator for compiling the results. These anonymised results will then be analysed using scientific methods, and presented in scientific conferences and published in medical journals.
- In the unlikely event of an incidental finding on your scan, which the expert looking at your scans considers to be important for your medical team to know, he will send the report back to your treating team and will request them to break the code and link it up with your medical records for appropriate treatment / investigation as might be necessary. In this case, you will be excluded from the study, as it will no longer be possible to maintain your anonymity.

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**Expenses and Payments**

- You will not be paid for participating in this research, nor will you incur any expenditure.
- The cost of the scan will be covered by a research grant.

**What will I have to do?**

- Ordinarily, a patient is not required to undergo an MRI scan after ADP, however, if you were to participate in this study, you would be taken to the radiology department for your scan, but you would not be required to take any additional medicines.
- Every patient is routinely followed up, on a daily basis, after an ADP to monitor development of PDPH (headache), its severity, treatment received, and any associated symptoms. Normally it is done until the patient is discharged home, and then they are instructed to report back if the symptoms returned. By participating in this study, you would agree to similar follow up for one week, which will be conducted in person by a member of the research team if you were in hospital or over the phone if you would have gone home. Typically, such interview takes about 5 minutes to complete. The information received will be used to complete a questionnaire daily.

**What is the MRI scan?**

Magnetic resonance imaging (MRI) scan is a promising investigation tool, frequently used in other field of medicines (neurology, neurosurgery etc), that can provide high-resolution images of the spinal cord, surrounding membranes, spinal fluid and its leakage into the epidural space.

**Do all the patients undergo MRI scan?**

No. Ordinarily, patients experiencing PDPH undergo MRI only to investigate and help with the diagnosis when the Epidural Blood Patches repeatedly fail to resolve the symptoms, where a serious complication is suspected.

**What are the possible disadvantages and risks of taking part?**

Although MRI scan is a very safe investigation tool with, to date, no known serious side effects or risks attributed to it, however, minor problems associated with MRI scan include: claustrophobia (fear of closed spaces), noisy and cold ambience, transportation to scanner causing a separation from the newborn, and exacerbation of headache during transportation. Patients with permanent metal implants, and pacemakers cannot undergo MRI.

We shall aim to keep the scan results anonymised, hence you, or your treating physicians, will not be informed about the scan results. That is because so far there is no scientific data available to suggest that MRI scan results can safely and reliably guide treatment of PDPH. There is a theoretical risk of your treatment getting influenced by the scan results, hence it will be appropriate not to release the scan report other than for its use in the research.

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In the unlikely event of an Incidental finding of serious nature identified during reporting of MRI scan, the treating team will be immediately notified for their appropriate intervention. Code will be broken to identify the patient, and the patient will then be excluded from the study as it will no longer be possible to maintain anonymity.

**What are the possible benefits of taking part?**

There are no financial or treatment incentives for participating in this research, however in the rare event of an incidental finding of serious nature, identified on MRI Scan, could benefit the patient from diagnosis of asymptomatic anomalies which otherwise might go undetected.

**Involvement of your GP**

Your GP will be informed about your decision to participate in the research project. That will help in future if you would require further investigations / treatment as a result of any incidental findings on your scan.

**What happens to the MRI scan images?**

The images will remain on the hospital computers, like any other medical records, kept about you, and those will be available for use for any other medical treatment that you might require for any related or unrelated condition in future. Those will be subjected to the same standard of protection and security as is the legal requirement. The coded / anonymised copies of the images sent to the expert for reporting for the study, will be deleted after a fortnight.

**Can I withdraw from the study?**

*Your participation in the trial is entirely voluntary. You are free to decline to enter or to withdraw from the study any time without having to give a reason. If you choose not to enter the trial, or to withdraw once entered, this will in no way affect your future medical care.*

**What if there is a problem?**

*If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service complaints mechanisms should be available to you.*

*Any complaints about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.*

*If you have any concerns about any aspects of this study, you should ask to speak to the researcher who will do their best to answer any questions (contact number). If you remain unhappy and wish to complain formally, you can do this*

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*through the NHS Complaints procedure. Details can be obtained from the hospital or at the PALS (Patient Advice and liaison service) office.*

**Will my taking part in this study be kept confidential?**

*All information which is collected about you during the course of the research will be kept strictly confidential and any information about you which leaves the hospital will have your name and address removed, and replaced with a code, so that you cannot be recognised except in the event of an incidental finding of serious nature on your scan. In that case, your data will no longer be used in the study to preserve your privacy.*

**Who has reviewed the study?**

*The study has been reviewed by the National Research and Ethics Committee (NRES Committee North West - Greater Manchester North) and the Research and Development departments of the participating hospitals.*

**Funding**

*This study is funded by the National Institute of Academic Anaesthesia on behalf of Obstetric Anaesthetists Association.*

**Who can I contact for further information?**

We would be happy to address any questions or issues that may arise. We can be contacted through your hospital switch-board (see below), asking for the anaesthetic secretary (during office hours) or the duty anaesthetist for maternity (out of hours) who will then pass on the message to us to call you back at the number that you would leave with them.

Telephone:

If you have any general comments or concerns you may email the Research Coordinator, Dr Amer Majeed at amer.majeed@docotrs.org.uk, or Chief Investigator, Dr Roshan Fernando at roshan.fernando@uclh.nhs.uk .

If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Patient Advice and Liaison Service (PALS) at the following numbers or email addresses:

Telephone:

Email:

**Thank you for agreeing to participate.**