Patient Information Sheet

Title of study:

An investigation of the neuroimmune effect of pulsed radiofrequency treatment (PRF) of the dorsal root ganglion (DRG) in chronic cervical and lumbosacral radicular pain

Introduction: You have been diagnosed with nerve pain that we call radicular pain. A number of diagnostic and treatment options exist. We perform a diagnostic local anaesthetic block in theatre for patients like you to confirm the diagnoses. If this block gives good pain relief, following review in our clinic, we proceed to steroid injections to the nerve or pulsed radiofrequency (PRF). Unfortunately, steroid injections are associated with rare, but sometimes serious, side effects. PRF treatment carries less risk. PRF has become popular because of its good safety profile. While we understand that steroids have an anti-inflammatory effect, our understanding of the effect of PRF in humans is limited.

We have recently performed a study that suggests that it may work by reducing the inflammatory cells in the spinal fluid. We have designed this follow-up study to evaluate how PRF affects the cells in your spinal fluid and to quantify the benefit of PRF in patients like you. Enrolling in the study will not significantly alter your pain management. Normally, patients like you attend the pain clinic and theatre for review and injections (2-3 visits). Involvement in the study means that your injection will take an additional 2 minutes of theatre time. We will also require a sample of spinal fluid (lumbar puncture) before the procedure and 3 months after the procedure. We will ask you to fill out a number of questionnaires (10 minutes to complete) on 4 separate occasions over 6 months.

Procedures: We will invite you to participate in this study if: you're over 18 years old, have moderate to severe nerve pain coming from a disc bulge that is present for over 3 months, and not responding to medications or exercise.

We will ask you to attend the day-ward for your diagnostic nerve block. You will complete questionnaires for 10 minutes. They give us an idea of how intense your pain is, and how it impacts on your life. You will complete the same questionnaire at 1 month, 3 months and 6 months post-treatment. A research nurse will contact you by phone to do this.

A lumbar puncture is performed before the nerve block. This involves inserting a thin needle in the lower back. We take a small sample (2ml) of spinal fluid for analysis in the laboratory. It takes about 1 minute to perform.

For the nerve block you will lie on a theatre bed, we will clean your skin with an antiseptic and we will take an Xray of your spine. We will give you local anaesthetic to numb your skin, and insert the needle beside the target nerve. An independent nurse will decide whether you receive the PRF treatment with your local anaesthetic block or just a local anaesthetic block on its own. Following the procedure we bring you to the recovery room for around 30 minutes, and the research nurse will see you to assess your pain relief.

You will be discharge soon after this if you're feeling well. At one month the research nurse will contact you by phone for 10-15 minutes to complete the questionnaires. At 3 months we will assess you in the clinic. We will also repeat your lumbar puncture and send 2ml of your spinal fluid to the laboratory. If you received PRF to the nerve we'd expect you to be experiencing peak pain relief at this point. If you continue to have unacceptable levels of pain we will schedule you for another intervention. You will be contacted at 6 months to complete the questionnaires. You will be informed at this point if you received a PRF treatment or not.

Benefits: You will receive more frequent reviews from medical and nursing staff (compared to patients not in the study) during the 6 months of the study. This study will also help to clarify the role and usefulness of pulsed radiofrequency in patients like you. As our knowledge of the therapy improves, so too will the care of patients with the same pain you experience.

Risks: Performing PRF before a standard diagnostic nerve block does not pose any additional risks to you. Your procedure will be prolonged by 2 minutes because of the PRF treatment, but you will not experience additional pain. The 2 lumbar punctures are rarely associated with infection, bleeding, nerve damage and headache. The risk of serious complications is < 1 in 1,000 cases, and we have not reported any of these complications in our previous studies.

Exclusion from participation: Your doctor has told you that you cannot be in this study if any of the following are present: dementia, poor English, cancer, back fractures, diseases like multiple sclerosis, serious infections, pregnant patients, previous back surgery, recent injections to the back, bleeding disorders, psychiatric disorders, allergies to the medications we use, regular use of anti-inflammatories and opioids, and patients who do not get good pain relief from the nerve block.

Alternative treatment: You do not have to be a part of this study to be treated. There are other medications available that can be used to treat your complaint and your doctor has discussed this with you.

Confidentiality: Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the hospital.

Compensation: Your doctors are covered by standard medical malpractice insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation: You have volunteered to participate in this study. You may quit at any time. If you decide not to participate, or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study.

Stopping the study: You understand that your doctor or the sponsoring company may stop your participation in the study at any time without your consent.

Permission: This study has hospital Research Ethics Committee approval.

Further information: You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr Connail McCrory who can be telephoned at (01) 4103952. If your doctor learns of important new information that might affect your desire to remain in the study, he or she will tell you.

CONSENT FORM

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Agreement to Consent

This study and this consent form have been explained to me. My doctor has answered all my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study.

I have read, or had read to me, this consent form and the patient information sheet. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement.

Participants's Name: _____

Participants's Signature:_____

Date:_____

Date on which the participant was first furnished with this form:_____

Statement of investigator's responsibility: I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Physician's signature:_____
Date:_____

Keep the original of this form in the participant's medical record, give one copy to the participant, and keep one copy in the investigator's records.