Patient information leaflet:

Study:
An investigation of the effect of amitriptyline on Cerebrospinal Fluid concentrations of TNF alpha, NGF, BDNF, VEGF and MCP-1 and quantification of cellularity of CSF in patients with chronic lumbar radicular pain.

Introduction:
You have been offered inclusion in this study because you have radicular pain (nerve pain, sciatica). This is treated with tablets like amitriptyline and a procedure called pulsed radiofrequency (prf), which is standard practice. We are doing this study to find out how the tablet amitriptyline works in nerve pain.

Procedure:
During the first procedure of prf we will take a small sample of spinal fluid using a very thin needle. This is done in our day surgery and you can go home on the same day. It will add 1-2 minutes on to the procedure time. The risk involved in this is very small and includes a 1/400 chance of a headache and a lower chance of infection and bleeding. You will then be started on the tablet called amitriptyline for 6 weeks and take it at night time until the second procedure of prf on a different affected nerve. We will take a second small sample of spinal fluid during the second procedure.

Benefits:
PRF and amitriptyline are treatments we use as standard for nerve pain. You can still receive either of these treatments or alternatives if you do not wish to participate in this study. Inclusion in this study offers no benefits other than to progress our understanding of the use of amitrityline in chronic pain.

Risks:
There is risk of infection, bleeding, nerve damage and headache related to pain procedure and spinal fluid sampling. However, this is rare. The methods used are well established in the St. James Pain Medicine unit and have already been demonstrated to be safe.
The tablet amitriptyline has some side effects like drowsiness and dry mouth. You can stop taking this medication at any time; you can also refuse to have the second prf treatment.

Exclusion from participation:

You cannot be included in this study if you are pregnant, breast- feeding, on anticoagulation or corticosteroid therapy, having active infection, have history of stroke and significant psychiatric problem.

Alternative treatment:

All patients with radicular pain are offered amitriptyline and/or PRF therapy. You do not have to be a part of this study to be treated.

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 Your name will not be published and will not be disclosed to anyone outside the hospital.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:

If 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 may stop your participation in the study at any time without your consent but you will never be deprived of treatment.

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 Jonathan Royds who can be contacted via the hospital switchboard. If your doctor learns of important new information that might affect your desire to remain in the study, he or she will tell you.