Patient Information leaflet :

Title of Study: An investigation of the effect of different methods neuromodulation on Cerebrospinal Fluid concentrations of TNF alpha, NGF, BDNF, VEGF and MCP-1 and quantification of cellularity of CSF in patients with failed back surgery syndrome and complex regional pain syndrome.

Introduction:
You have been selected to take place in this study because you are going to have a spinal cord stimulator. This study is being done to see how the stimulator works and affects proteins in the spine using different settings. We will also be looking at how the different settings improve your pain and function.

Procedure:
If you a agree to participate you will come in to the day ward as planned. We will take a small sample of spinal fluid from your back (before the stimulator is put in) using a thin needle. We will then take a second sample of spinal fluid from your back during your follow up visit. The risk of any complications is low for this procedure and includes a 1/400 chance of headache and much lower risk of nerve damage.

Benefits: Inclusion in this study offers no benefits other than to progress our understanding of the use of spinal cord stimulators in chronic pain.

Risks:
There is risk of bleeding, nerve damage and headache related to spinal fluid sampling. However, this is rare (see risks of lumbar puncture below). The methods used are well established in the St. James Pain Medicine unit and have already been demonstrated to be safe.

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.

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 Your name will not be published and will not be disclosed to anyone outside the hospital.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

Risks of Lumbar Puncture:

Risks:

Common >5%:

- You may have mild backache for a few days; this would be similar if having PRF alone
- Shooting pain down legs during the procedure is common but resolves after the needle is withdrawn

Uncommon 1-5%:

- Headache with the needles we use is rare but can be severe and last for a few days. It may require intervention if persists

Rare:

- Nerve damage is between 1/10,000 – 1/30,000, this may result in numbness or loss of power in your legs. This will likely improve over 6 months.
- Infection occurs in roughly 1/100,000 patients and would require antibiotics and/or surgery
- Bleeding and clots can occur in 1/200,000 patients and requires urgent surgery

References:
Cook TM, Counsell D, Wildsmith JA. Major complications of central neuraxial block: report on the Third National Audit Project of the Royal College of Anaesthetists†. British journal of anaesthesia. 2009 Feb 1;102(2):179-90.