STUDY PARTICIPANT INFORMATION SHEET

Pain in Neuropathy Study - (PINS) – CTS Sub study

You are being invited 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.

Part 1: tells you the purpose of this study.

Part 2: gives you more detailed information about the conduct of the study and what will happen to you if you take part.

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.

Thank you for reading this.

PART 1

What is the purpose of this study?

Carpal tunnel syndrome is the most common compression neuropathy and results from compression of a nerve that travels through a narrow tunnel in the wrist. Carpal tunnel syndrome may lead to numbness to touch or temperature or pins and needles in the affected hand. In some instances carpal tunnel syndrome can become painful – this is called neuropathic pain. The reasons why one person will develop a painful carpal tunnel syndrome and another will not is not known.

This study is designed to look, in detail, at the changes in sensation occurring as a consequence of having carpal tunnel syndrome. We will also be examining the effect that carpal tunnel syndrome and neuropathic pain has on peoples’ functionality and quality of life. The study involves you filling in questionnaires, undergoing detailed sensory testing of your skin, the taking of a small skin biopsy and the testing of some of your small nerve fibers (see details below).

All labels, which are identifiable as being related to you, such as name, address, date of birth, will be removed prior to analysis of any questionnaires or samples.

Why have I been chosen?

You have been invited to participate in this study, as you either have carpal tunnel syndrome and you are over 18 years of age and you are not pregnant. Even if you have no symptoms of pain or neuropathy we would still like to include you. Or you may have been invited to participate in this
study as you are healthy with no indication of nerve related problems and your results will therefore serve as control data in our study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

PART 2

What will happen to me if I take part?

If you are interested in taking part in the study, an appointment with a research doctor will be made at a time convenient for you.

The study can be completed in a single appointment, which will take approximately 2-3 hrs as well as filling in a number of questionnaires which takes 45 minutes:

During this appointment you will be able to ask any further questions that you may have regarding the study. We will also check if you are eligible for the study. If you wish to take part in the study, you will be asked to sign a consent form and given:

1. **Questionnaires:**
   - A simple diary in which we would like you to record your daily (if any) pain twice a day for 7 days.
   - A questionnaire about you, your past medical history, medications you are or have been taking,
   - Questionnaires, which will take approximately 45 minutes to complete will ask you about the quality of symptoms, functional deficits as well as the impact of symptoms on your mood, sleep and quality of life.

   These can be completed in 45 minutes and posted back to us.

2. **Blood Sample:**

   We will take 30mls blood sample (approximately 3 dessert spoons), this sample will be stored in a locked freezer located at King’s College London and then samples will be analysed looking for genes and their relationship between neuropathy and the risk to develop pain, and/or its severity. We want you to understand that these genetic analyses will be strictly restricted to neuropathy and pain, all samples will not have your name, address or any other label from which you could be identified. Because these tests are performed on a research basis and can’t predict the risk of developing pain on an individual basis you will not receive these results.

   In addition during this appointment a research doctor will review your medical notes.

3. **General Neurological Examination:**
We will examine you clinically for muscle strength, reflexes and changes in your skin’s ability to feel things in your arms and legs. We will also measure your weight, height, and blood pressure.

4  **Quantitative Sensory Testing of both hands, your neck and leg:**

This is a more detailed method of testing the function of the small sensory nerve fibres in your skin, which detect changes in temperature, pressure, sharpness and touch. It is in routine diagnostic use in our clinic.

Your ability to sense changes in temperature is determined using a small probe applied to your skin which changes temperature, i.e. becomes cool or warm. You will be asked to say when you can feel any change.

Your ability to detect light touch is determined using very fine filaments, again you will be asked to say when you can feel them.

For sharpness a small probe designed not to puncture the skin, is applied to your skin. You are asked to say when it begins to feel sharp.

A blunt pressure gauge is used to apply pressure. You will be asked to say when the pressure just begins to become uncomfortable.

We will also lightly touch a small area of your skin with a Q-tip, cotton wool, a paint brush and a tuning fork and ask you to describe the sensation that you experience.

Some of these tests may cause slight discomfort, however you will be able to stop at any point if you are not happy.

5  **Small Skin Biopsy of your hand:**

A very small: 3mm (~1/10 inch) circular piece of skin (skin biopsy) will be taken usually from your finger after some local anaesthetic to numb the area. A small plaster will be applied to keep it clean afterwards. This procedure is routine practice in dermatology clinics and is being increasingly used in pain and neurology clinics; it is deemed to be safe and has a low risk of infection and scarring. However both of these can rarely occur. Healing usually occurs in 7-10 days.

This skin biopsy will then be examined under a microscope to determine the degree of small nerve fibre damage (if present) in your skin.

We will also keep the remaining unused tissue in a locked freezer at King’s College London or University of Oxford for future biochemical analysis investigating neuropathy and neuropathic pain.

The samples will not have your name, address or any other label from which you could be identified.

6  **Nerve Conduction Studies:**

For measuring how your nerves are conducting the information from the periphery to the brain and from the brain to your muscles, we will use neurophysiologic tests. We will attach some electrodes and a small electrical current will be applied to assess the ability of your nerves to transmit electrical impulses.
The procedure is extremely safe, and only causes mild discomfort. If you have done this test before, we can reuse the data and do not have to repeat it.

In addition during this appointment a research doctor will review your medical notes.

If at any point during the study you wish to convert a single appointment to a double appointment, you can request to do so.

You are also able to take breaks, for whatever reason, at any point during the study if you wish.

What are the possible disadvantages and risks of taking part?
The main disadvantage is that you will need to give up approximately 3 hours of your time to take part. Another disadvantage is that you will be required to travel to one of the study sites (either King’s College London, John Radcliffe Hospital or Chelsea and Westminster Hospital) for an appointment. We will reimburse your travelling expenses if required.

Additionally as a result of the testing, we may discover that you have a neuropathy which you were previously unaware of. We would of course ensure that you would be followed up after the study, and given advice and treatment. However, some people may not have wanted to know.

What are the possible benefits of taking part?
We cannot promise the study will help you, but the information we get might help improve the treatment of people with neuropathy.

In particular we hope to determine the relationship between changes in skin sensation and the degree of small nerve fibre damage present in the small skin biopsies.

As a consequence of all this we maybe better able to identify patients who have, or are at risk of developing a painful neuropathy following carpal tunnel syndrome. This may help us to better treat this problem in the future. We will also be developing validated clinical tools to help us diagnose and assess carpal tunnel syndrome in our clinics.

What if something goes wrong?
Oxford University and King’s College London holds insurance policies, which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that King’s College or Oxford University are at fault.

This does not affect your legal rights to seek compensation. If you are harmed due to someone’s negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigators.

Will my taking part in this study be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential. We will send anonymised data from these studies to University computers for analysis and also include it in computer databases which are used to store and analyse data about neuropathy and pain; these are the London Pain Consortium and the German Neuropathic Pain
Network databases. By comparing the information from this research with that from other research we will be able to learn far more about these conditions.

**Will my GP be informed?**
As part of good clinical practice in medical research it is recommended that we inform your GP of your participation in this study. However if you do not want your GP to be informed, we will respect your wishes. This will not affect your ability to take part in this study.

**What will happen to the results of the research study?**
We will make the research and medical community aware of the results of this study by the normal process of publication in scientific journals and presentation at professional conferences. If you wish to be informed of these publications we can arrange to do so. No data will be identifiable as from you in the publications.

We will use the blood samples to look for specific genes that are associated with the development of neuropathy and/or painful neuropathy.

We will ask for your permission to contact you in the future. We may then invite you to participate in further research in the future.

**Who is organising and funding the research?**
This study is being organised by Department of Neurorestoration, Wolfson CARD, King’s College London, The Nuffield Department of Clinical Neurosciences and The Wellcome Trust is the charity that is funding this research.

**Who has reviewed the study?**
This study was given a favorable ethical opinion by The Riverside Ethical Committee.

**Contact for Further Information:**
For further information regarding this study please contact:
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