Participant Information Sheet

SENSORY NERVE TRANSFER TO RESTORE PLANTER SENSATION IN LEPRSOY NEUROPATHIC FEET

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One member of our team will go through this information sheet with you and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

Who is organising and funding the study?

The study is being organised by the Anandaban Hospital, The Leprosy Mission Nepal in collaboration with the University of Birmingham, UK. The study is funded by the UK National Institute for Health Research.

What is the purpose of the study?

In Leprosy due to nerve damage there is loss of sensation leading to ulcers, claw toes which leads to deformity which might hamper the quality of life and capacity of people. Nerve transfer is one of the new and safe procedure to restore the sensation in the foot.

The purpose of our study is to test a new treatment method that can restore the sensation of the anaesthetic foot that may help to prevent from further deformity and recurrence of ulcer too. This treatment can be done if you are willing to take part. You will be examined first and if you are eligible you will go for a nerve transfer surgery. The surgery is generally done under spinal anaesthesia where your healthy nerve called saphenous nerve will be connected to your damaged

nerve of the leg which is called Posterior Tibial nerve. After surgery plaster back slab will be applied for three weeks and follow up will be done to know the status of your foot. So, that is what this study is about – doing a 'fair test' to see if this restores the sensation or not.

Why have I been asked to take part?

You have been invited because you have been leprosy affected person with anaesthesia on your foot and/or ulcers in your foot.

Do I have to take part?

No. It is up to you to decide to take part or not. If you don't want to take part, that's ok. Your doctor will still care for you and your decision will not affect the quality of care you receive.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

If you are willing to take part in this study, we will first ask you to sign a consent form which is your indication that you understand the study and agree to take part.

Then you will be evaluated, do an interview and physical examination. If you meet the study's criteria, and you wish to participate, you will go through nerve transfer surgery which was as explained above. If you get enrolled in the study, you will have to be admitted and stay for about one month at hospital. You will be discharged only after removal of plaster back slab.

It is important that you realise that treatment is not always effective. If you agree to take part of this study, we will ask you to complete different questionnaires. You will be called for follow-up at three month and at six months after enrolment for the study.

What will I have to do?

You will be expected to be admitted in hospital during the treatment period and follow ups up to 6 months after surgery. You have to answer the entire question asked to you. This will help us to gather information about you and your progress during the study period.

What information will be collected?

Only simple information about you, your diseases history, treatment for your ulcer and for leprosy and how it affects you will be collected. This will include your name, but you will only ever be viewed by your participant number. We will keep this information separate from your address.

We will also take photographs of your foot and ulcer as per needed to see how well it is healing. These photographs will only ever be viewed by your participant number. We may also make video of your surgery.

What will happen to information collected about me?

All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Data may be sent to other study staff at University of Birmingham, but this will be anonymised. This means that any information about you which leaves the hospital/surgery/clinic will have your name and address removed so that you cannot be recognised.

Your doctor will send some details about you to the study team at university of Birmingham, who will store it securely. Your personal details will be kept in a different safe place to the other study information and will be kept for at least 10 years after study completion. All the data will be securely stored in safe place.

The collected data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, please refer to the University of Birmingham Research Privacy Notice which is available here: https://www.birmingham.ac.uk/privacy/index.aspx or by contacting the Information and Data Compliance Team at: dataprotection@contacts.bham.ac.uk.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can also contact Dr. Indra Bahadur Napit who is the principal investigator of this study for any queries. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Richard Lilford, University of Birmingham UK by emailing at r.j.lilford@bham.ac.uk

The study holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell your doctor that you don't want to be in the study anymore. Your doctor will still care for you.

You can withdraw from treatment but keep in contact with us to let us know your progress. Information collected may still be used.

What will happen to the results of this study?

The study results will be published in a medical journal so that other doctors can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who has reviewed the study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nepal Health Research Council (NHRC …….).

Who should I contact if I want further information?

Dr Indra Bahadur Napit, Anandaban Hospital, TLM Nepal, Tel: +977-9851136027,

email: indran@TLMnepal.org

Professor Richard Lilford, University of Birmingham, UK r.j.lilford@bham.ac.uk

Nepal Health Research Council, Ramshahpath, Kathmandu: 014254220

****Thank you for taking time to read this information leaflet. If you think you will take part in the study, please read and sign the consent form.****

CONSENT FORM

SENSORY NERVE TRANSFER TO RESTORE PLANTER SENSATION IN LEPRSOY NEUROPATHIC FEET

Title of Project: SENSORY NERVE TRANSFER TO RESTORE PLANTER SENSATION IN LEPRSOY NEUROPATHIC FEET

Name of Researcher(s): Dr Indra Bahadur Napit, Anandaban Hospital, TLM Nepal and Professor Richard Lilford, University of Birminigham, UK

A. I _____
   understand that doctors at Anandaban Hospital and at University of Birmingham are involved in research of nerve transfer to restore nerve sensation. This study will look at how effective is nerve transfer to restore the sensation of my foot.
B. The study has been explained to me.

C. I confirm that I am 18 years old or above.

D. I agree to have photographs and videos taken during the ulcer dressing.

E. I agree that my collected data be used for further research in future*.
F. *Please note that participants may say 'NO' to this question and still take part in the study.

G. I can decide to leave the study at any time for any reason and will still receive other treatment from the hospital for my condition.

H. I understand that my name will not be revealed in any published material concerning this study. I understand that my notes will be treated with maximum confidentiality and will only be accessed by staff directly involved in the Study or the monitors of the Study.

I. I have received enough information about the study in a language I understand. I had the opportunity to discuss it and ask questions, and my questions have been answered to my satisfaction. I understand that participation is voluntary and that I am free to withdraw my consent at any time. I freely consent to participate in this research study and to allow treatment and tests to be performed on me as explained.

J. I understand that I can be requested anytime to terminate my participation in the study if the need arises. I will be given full explanation of the reason and will still receive standard treatment.

K. I agree to take part in the study.

Printed Name & Signature (or fingerprint) Date

Name of Participant _____

Signature/Fingerprint _____ _____/_____/20____

Name of Witness _____

Signature/ Fingerprint _____ _____/_____/20____

Name of Researcher_____

Signature _____ _____/_____/20____