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Sensory nerve transfer to restore loss of sensation in leprosy feet

Submission date
14/03/2024

Recruitment status
Stopped

Registration date
20/05/2024

Overall study status
Stopped

Last Edited
09/06/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
This particular protocol is concerned with nerve transfer surgery of leprosy neuropathic feet with loss of sensation for 5 years. It will take place in Anandaban Hospital, The Leprosy Mission Nepal in Kathmandu, Nepal. The study aims to implement the saphenous nerve (SN) to posterior tibial nerve (PTN) nerve transfer operation in Anandaban hospital and ensure that it has effects consistent with the literature on the restoration of the sensation at the plantar surface of feet. The study will also estimate the costs of the procedure and conduct a full health economic analysis to estimate the cost-utility of the intervention. The study is designed as a single-center, prospective interventional case series study and health economic analysis.

Who can participate?
Adult patients aged 18 years old and over with loss of sensation in the plantar surface of the feet due to leprosy neuropathy

What does the study involve?
Participants will receive a surgical procedure with transfer of the SN to the PTN followed by a decision analytic model. The main outcome is the restoration of the sensory function of the plantar region of the foot. Other outcomes include a quantification of resources used and the collection of cost information. The sample size will be 15 consenting participants who will be followed up at 3 and 6 months from enrolment.

What are the possible benefits and risks of participating?
The possible benefits for the participants will be the regain of lost sensation on the plantar surface of the foot. This regain of lost sensation will protect them from recurring ulcers which may have a positive impact on the overall quality of life.

This study involves surgery under local or general anesthesia. This may have some minor side effects on the participants. Additionally, there is some risk of localized infection at the site of incision

Where is the study run from?
Anandaban Hospital, Nepal

When is the study starting and how long is it expected to run for?
September 2023 to June 2025

Who is funding the study?
The Leprosy Mission Nepal

Who is the main contact?
Mr. Sushil Khatiwada (Finance Manager), Sushilk@tlmnepal.org

Contact information

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Scientific, Principal investigator

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Additional identifiers

National Institute for Health and Care Research (NIHR)
200132

Protocol serial number
Protocol version 0.8

Study information

Scientific Title
Sensory nerve transfer to restore planter sensation in leprosy neuropathic feet - a pilot study and health economic analysis

Study objectives
The surgical transfer of the saphenous nerve to the posterior tibial nerve will help in regaining sensation at the plantar surface of the foot.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/08/2024, Nepal Health Research Council (Ramshah Path, Kathmandu, P.O.Box 7626, Nepal; +977 1 4254220; nhrc@nhrc.gov.np), ref: 219 (102_2024)

Primary study design
Observational

Study design
Single-center prospective interventional case series study and a health economic modelling study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Patients with loss of sensation in the plantar surface of the feet due to leprosy neuropathy

Interventions
This study investigates the surgical transfer of the saphenous nerve to the tibialis posterior at ankle level. The surgery will be under spinal or general anesthesia with a tourniquet at the affected limb to control bleeding. Two parallel incisions will be made, one anterior to the medial malleolus just over the saphenous vein and a second incision posterior to the medial malleolus over the tarsal tunnel. The length of each incision will be about 7-8 cm. After the skin incision anterior to the medial malleolus the saphenous nerve will be identified, which runs alongside the great saphenous vein. Two branches of the saphenous nerve (anterior and posterior) will be dissected and freed from the surrounding fascia for a length of 7 cm. At this level, both the branches contain 5–6 fascicles. The second skin incision will be made posterior to the medial malleolus where the posterior tibial nerve will be identified in the grove between the medial malleolus and the Achilles tendon after cutting the flexor retinaculum, it will be dissected for a length of about 5 cm. An epi-neural incision of the posterior tibial nerve will be made and 5-6 sensory fascicles will be identified using intra-operative electric stimulation. Those fascicles which did not evoke motor contractions of foot muscles will be considered sensory fascicles. These fascicles will be cut proximally and be re-routed towards the saphenous nerve. The saphenous nerve will be cut distally and joined (anastomosis) to the sensory fascicles of the

posterior tibial nerve, using 8-0 nylon epi-neural repair. Then the skin wound will be closed and a below-knee plaster back slab will be applied for 3 weeks. The plaster back slab will be removed after 3 weeks, and the patient will be instructed to use footwear with microcellular rubber (MCR) insole while walking. The data collected will include information on basic demographics, clinical data including co-morbidity conditions, laboratory tests, x-ray, sensory assessment, ulcer information and size of ulcer (for patients with ulcers), quality of life and bone mass density, The post-operative sensory assessment will be done at 3 and 6 months in all three territories of the sole. Sensory recovery will be graded according to the MRC scoring system. Healing of ulcers (proportion of healed ulcers) in the feet will be also assessed for those who have ulcers in the feet. Bone density data will be collected at baseline and endline. Photographs of affected feet will be taken with a tablet at baseline, 3 and 6 months.

Healing of ulcers will be confirmed by the local clinician based on his/her clinical judgement. To confirm an ulcer is healed, there should be complete epithelialization on the ulcer surface. The ulcer-related data will be collected for the participants who have foot ulcers only. Additionally, standardized ulcer pictures will be taken on the day of enrollment and then three and six months follow-up after enrollment. The pictures of the foot ulcers will be captured with the help of a built-in camera on a tablet (Samsung Galaxy Tab 6). The photograph will be captured perpendicular to the ulcer surface. For calibration purposes, a 3cm size clean paper ruler with the date and participant's trial identification number will be placed in the photograph frame above or below the ulcer but at the level of the skin. The photographs will be sent to an independent assessor for measurement. The independent assessor will measure the ulcers with the help of PictZar Digital Planimetry Software (http://www.pictzar.com/).

Estimating cost utility from a health service perspective:
Treatment costs will be estimated. Net health service costs will be estimated by applying local reference costs. Potential savings from reduced hospital admissions and reduced healed cases in the community will be estimated from data on admission rates for people with ulcers and interventions with nurses or community health workers who serve people affected by leprosy. This method will be extended to include the costs of further complications as per the disease progression model above. These costs will be subtracted from the intervention costs to yield net costs (possibly yielding a negative quantity i.e. saving). Cost-utility will be constructed by dividing the cost by the DALY function, conducting a probabilistic sensitivity analysis (at least over the above distributions) and comparing the result to various reference willingness to pay thresholds in exemplar countries.

Estimating cost utility from a Societal perspective:
It could be argued that such a perspective is required only if the health perspective does not allow the intervention to dominate. However, the research team think it would be informative to model a wider perspective. These should include costs the person must bear to access treatment and lost productivity. The analysis will focus on the latter because costs to travel to the hospital are very variable across the world and are arguably not material when set against loss of earnings.
To measure the effects on earnings, days lost from work will be estimated and then the contingent losses in earnings. National figures will be used to estimate the proportion of people in the labour market and the proportion of those who work in labour-intensive versus sedentary industries. It will be assumed (in a base case) that those in manual jobs do not work while they have an ulcer (since off-loading is essential to ulcer healing). National reference costs will be used to calculate the loss of earnings for manual workers over the mean duration of the healing phase of a plantar ulcer. A reference group will be created to ensure that the estimates are realistic and to suggest alternative quantities for illustrative deterministic sensitivity analyses.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Restoration of the sensory function of the plantar surface of the foot measured using the MRC scoring system at baseline and 3 and 6 months

Key secondary outcome(s)
1. The proportion of ulcers healed measured by the local clinician based on his/her clinical judgement and photographs sent to an independent assessor for measurement at baseline, 3 and 6 months
2. Economic cost analysis from a health service perspective and wider societal perspective measured using data collected in medical records after six months of follow-up.

Completion date
30/06/2025

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patient with loss of sensation of the foot (inability to feel monofilament of 10 grams) for a duration of more than one but less than five years
2. Patient with or without planter ulcers. Only non-infected ulcers will be included
3. ≥18 years of age
4. Patient who can provide informed consent
5. Completed multi-drug therapy (MDT) treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Key exclusion criteria

1. Any significant medical condition, laboratory abnormality, or psychiatric illness that would prevent the participants from participating in the study (e.g. HIV, chronic Hep B, chronic Hep C or TB patients under active treatment)
2. Pregnancy or breastfeeding
3. Patients with Erythema Nodosum Leprosum (ENL) or a leprosy reaction under steroid treatment
4. Any wound that has clinical signs of infection
5. Nerve conduction test velocity less than 40 ± 3.4 m/s and amplitude of 9 mV in saphenous nerve
6. Other conditions in the ankle/foot like the acute stage of Charcot's foot, complicated ulcers with Osteomyelitis, and acute neuritis with positive Tinel’s sign (tender swollen peripheral nerve)

Date of first enrolment
01/09/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Nepal

Study participating centre
Anandaban Hospital
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Sponsor information

Organisation
The Leprosy Mission Nepal

Funder(s)

Funder type
Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request and approval from the Principal Investigator, Dr Indra Bahadur, indran@tlmnepal.org

The data underlying the findings would require participant-level trial data to be made publicly available which could compromise patient privacy, and participants did not consent for their data to be made publicly available. We are however able to share non-identifiable participant-level data upon request with an appropriate data-sharing agreement in place.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			26/03/2024	No	Yes