

Laser for nerve injuries

Submission date 24/08/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/08/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A neuroma is a disorganized growth of nerve cells at the site of a nerve injury. Neuroma pain is a major cause of illness. Surgical success is only around 50%, but actual functional improvement may only be as high as 12.5%, with significant potential illness and cost. Studies exploring the use of lasers to stop the conduction of pain signalling through the nerve feeding the neuromas reported no return of symptoms at 56 months. Single bare fiber technology allows even smaller fluences to be used whilst targeting the nerve effectively. This type of treatment is a well-established practice in other aspects of plastic surgery, used successfully and with no/minimum death rates in other areas such as cosmetic surgery etc. This study therefore aims to replicate this success by exploring the use of a single bare fiber laser in the management of neuroma pain from neuromas after amputation.

Who can participate?

Patients aged over 18 years where medical and surgical intervention has been maximized, contraindicated, or refused, who have a targetable nerve feeding the neuroma. Participation in the study requires referral from the All Wales Peripheral Nerve Multi-Disciplinary Specialist Team.

What does the study involve?

Following routinely performed clinical ultrasound and an injection of local anesthetic needed for routine clinical care, the target nerve will be identified under ultrasound and a laser will be used to target it through micro fiber-optic systems. There will be a period of observation before being discharged and re-entering routine clinical care. A number of score sheets will be administered to monitor outcomes. Neuroma size will be measured by ultrasound, and clinical follow-up will be for up to 2 years.

What are the possible benefits and risks of participating?

Laser treatment has the potential to become a low-risk office-based procedure offering long-term pain reduction. Risks include no or limited success, skin blistering/thermal injury, over or under pigmentation of the skin, localised fat atrophy (breakdown), aggravation of pain, infection, injury to related integumentary structures (the body's outer layer); hematomas (collection of blood).

Where is the study run from?
Swansea Bay University Health Board (UK)

When is the study starting and how long is it expected to run for?
August 2020 to December 2024

Who is funding the study?
Ovidio Marangoni Research Fund

Who is the main contact?
Dr Ernest Azzopardi, ernest.azzopardi@wales.nhs.uk

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

264813

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 264813

Study information

Scientific Title

Transcutaneous laser for treatment of amputation neuromas

Acronym

TCLAN

Study objectives

Principal hypothesis: can pain caused by neuromas be improved by transcutaneous lasering (single bare fibre 1470 nm laser).

Secondary research questions:

Will transcutaneous lasering (single bare fiber 1470 nm laser) result in changed mobility scores?
Will transcutaneous lasering (single bare fiber 1470 nm laser) result in a change in the size of the neuroma?

Experimental hypotheses:

Principal research question:

HE1: Can pain caused by neuromas be improved by trans-cutaneous lasering (single bare fibre 1470 nm laser)?

Secondary research question:

HE2: Will transcutaneous lasering (single bare fibre 1470 nm laser) result in changed mobility scores?

HE3: Will transcutaneous lasering (single bare fibre 1470 nm laser) result in a change in the size of the neuroma?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/10/2020, London – Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048088, +44 (0) 2071048102, +44 (0)2071048388; surrey.rec@hra.nhs.uk), REC ref: 20/PR/0379

Study design

Interventional clinical study on a consecutive series of patients

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Amputation neuromata

Interventions

As part of routine clinical diagnostics, the following is performed, a neuroma is identified on ultrasound; the nerve "feeding" the neuroma is identified on ultrasound. Subsequently, a diagnostic injection of local anaesthetic is made. Temporary relief of pain is a positive diagnostic test for an amputation neuroma. These procedures are not part of the experimental protocol.

They are part of normal service provision. If a targetable nerve is identified, the patient is eligible for treatment. Subsequently, with the target nerve already identified under ultrasound, treatment is performed with Lasemar 1500 (Eufoton Trieste, Italy), which is a CE-marked device, class 4 medical device, bearing mark CE 0476 using its bare fibre attachment. The device has a wavelength of 1470 nm and will be used within its intended remit. Further, a risk assessment by the health board confirmed the intended intervention as a LOW-RISK procedure. Under ultrasound guidance, laser energy is directed into the nerve, downstream of the injection site. This technique therefore benefits from the analgesic effect of the local anaesthetic which has been injected for therapeutic purposes. Cooling is continued 5 minutes post-intervention to allow dissipation of any excess energy, skincare, and reduce the risk of complications. The patient then waits for 1 hour until reviewed and discharged.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Pain scores recorded on a 1-10 validated scale pre- and post-treatment

Key secondary outcome(s)

1. Mobility measured using the Disabilities of Arm, Shoulder and Hand (DASH) score for the upper limb and the Basic Amputee Mobility Score (BAMS) for the lower limb pre- and post-treatment
2. Neuroma size measured in mm through transcutaneous ultrasound pre- and post-treatment

Completion date

20/12/2024

Eligibility

Key inclusion criteria

1. Adult patients (aged >18 years)
2. Capable of giving informed consent
3. Any Fitzpatrick skin type
4. Have undergone amputation (any method) subsequently complicated by the development of reduction (stump) neuroma
5. The patient is not eligible, or declines, further conventional treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Photosensitising or photo-bio-modulating medications
2. Patients on psoralens
3. Patients suffering from any condition aggravated by near infra-red wavelengths
4. Patients suffering from porphyria
5. Patients on anticoagulants
6. Any condition where laser is contraindicated
7. Patients with overlying skin breaches or infection
8. Patients on anticoagulants
9. Patients with concomitant neurological conditions
10. Patients with a known history of altered sensation (e.g. Charcot's illness)
11. Patients objecting to receiving treatment with laser
12. Patients who are pregnant
13. Patients who object to their GP being notified.
14. Patients with no targetable nerve/s identified on ultrasound
15. Patients where diagnostic injection of local anaesthetic fails to confirm a targetable nerve

Date of first enrolment

20/10/2022

Date of final enrolment

20/10/2023

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Swansea Bay University Local Health Board

One Talbot Gateway, Seaway Drive

Seaway Parade Industrial Estate

Baglan

Port Talbot

United Kingdom

SA12 7BR

Sponsor information

Organisation

Swansea Bay University Health Board

ROR

<https://ror.org/04zet5t12>

Funder(s)

Funder type

Research organisation

Funder Name

Ovidio Marangoni Research Fund

Funder Name

investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the small number of recruits and requirement for data protection, unless in pooled anonymised form fulfilling current data protection requirements, confirming to GDPR legislation and successive UK specific legislation

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No