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Laser for nerve injuries

Submission date 24/08/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/08/2022	**Overall study status** Completed	
Last Edited 30/08/2022	**Condition category** Surgery	

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
Dr Ernest Azzopardi

ORCID ID
https://orcid.org/0000-0002-4511-0954

Contact details
c/o Mr Dean E Boyce Clinical Director
Department of Plastic Surgery
Swansea Bay University Health Board
NHS Wales
Swansea
United Kingdom
SA6 6NL
+44 (0)1792 702222
ernest.azzopardi@wales.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
264813

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
20/08/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

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

Sponsor details
1, Talbot Gateway
Baglan Energy Park
Baglan
Port Talbot
Wales
United Kingdom
SA12 7BR
+44 (0)1792702222
Rebecca.McGrath2@wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://sbuhb.nhs.wales/about-us/contact-us/

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

Publication and dissemination plan
The study's results will be published in a conference format (interim) and in a final format in a reputable, indexed peer-reviewed publication

Intention to publish date
12/12/2025

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