ISRCTN11703740 https://doi.org/10.1186/ISRCTN11703740

Can using two types of lasers together make burn scars look and feel better compared to usual care?

Submission date
23/08/2023

Recruitment status
Recruiting

Registration date
11/09/2023

Overall study status
Ongoing

Last Edited
06/11/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and aims
After a burn, some peoples' scars may become thick, raised and lumpy after the wound heals. This is called a hypertrophic scar and affects up to 6 out of 10 patients who suffer a burn injury. This can happen if you have an operation to treat your burn or if it heals with dressings. These scars are red and firm and can affect a patient's physical and mental health, causing itch, dryness, pain and problems with joint movement due to stiffness.
Laser is a relatively new way of treating burn scars. We need more scientific evidence to see whether laser is useful to treat burn scars. This study will combine two different lasers (pulsed dye laser and carbon dioxide laser) commonly used to treat scars to see whether they work better together and improve the way that you feel the scar looks. The combination laser will be compared to a single laser we already use (carbon dioxide laser) or no laser treatment.
The pulsed dye laser is designed to treat blood vessels and redness in your scar. The light heats tiny blood vessels in your scar which give it the red colour and damages them, causing bruising. This is a normal reaction to this type of laser and the research team are looking for this.

The carbon dioxide laser creates microscopic shallow holes in scars, which help them to mature and can improve feelings of tightness. Fractional laser can also make scars softer / flatter.
We want to see whether any symptoms caused by burn scars (for example, itch), get better with the laser treatment.

Who can take part?
• Adults over 18 years of age
• Hypertrophic (red raised) burn scar
• Scars which would ordinarily be managed by pressure garments and laser intervention
• All patients to be less than 3 months from burn wound being healed at point of recruitment.

What will the study involve?
Study visits are likely to be at the same time as usual appointments with the scar therapy team that you would attend if participants were not taking part in this study. If chosen to receive the laser treatment, participants will be invited to attend three additional appointments to receive

this treatment. Participants will be randomly selected into one of three groups.
• One group will receive standard care only (moisturiser, massage, pressure garments or silicone)
• One group will receive standard care and single laser treatment (carbon dioxide laser).
• One group will receive standard care and combined laser treatment (pulsed dye laser and carbon dioxide laser)

1. Standard care control group
The control group will attend for 3 standard care appointments in an outpatient clinic. This will be at regular intervals of 4 months, and each appointment will take around 30 minutes. Photographs will be taken of the scar and participants will be asked to complete two short questionnaires about how feel the scar looks and affects them on a day to day basis.

2. Treatment single and combined laser groups
The single and combined laser groups will attend hospital for 3 laser treatments, in addition to standard care appointments. There is a gap of 6 weeks between treatments. At each appointment, photographs will be taken of the scar and then an anaesthetic numbing cream will be applied to the scar for 60 minutes before the laser treatment.

The laser treatment is not usually painful however it may be uncomfortable. Once complete, a cool pack will be put to theskin, which helps relieve any discomfort. Vaseline ointment will be applied to your scar together with a non-stick dressing. Each appointment will last around 90 minutes total.

As well as the three laser appointments, participants will be asked to attend 3 standard scar therapy appointments in an outpatient clinic. This will be at regular intervals of 4 months (before laser treatment then regularly after), and each appointment will take around 30 minutes. Photographs will be taken of the scar and participants will be asked to complete two short questionnaires about how you feel your scar looks and affects you on a day to day basis. A member of the research team will examine the scar.

What are the possible advantages of taking part?
By taking part, we will learn whether combined laser treatment improves scars for patients. This study may benefit future burns patients.

What are the risks of taking part in this study?
Laser treatment makes the skin feel warm and leads to bruising and tiny holes in your scar; this is what we expect to see with the treatment. The scar being treated will be cooled with a cold pack for your comfort during treatment. Other side effects may include redness, some discomfort or swelling. It is possible that it may blister, scab or flare-up. All these effects are likely to fade or heal within 7 to 10 days.
Laser treatment may be less effective for patients with darker skin types. There is also an increased risk of permanent changes to skin colour (becoming darker or lighter). If participants have a suntan or fake tan at the time of laser treatment, they will be asked to return in a few weeks once this has faded.
Sometimes, the questionnaires used in studies such as these may bring back some feelings that remind participants of the time they had their burn injury. Clinical psychology support will be offered if this is a concern.

Where is the study run from?
The study is run from the Newcastle upon Tyne NHS Foundation Trust (UK))

When is the study starting and for how long is it expected to run for?
October 2020 to June 2027

Who is organising and funding the research?
The study is being coordinated by the Newcastle Hospitals NHS Trust and is funded by the Royal College of Surgeons of England and the Blond McIndoe Research Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301064

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49954, IRAS 301064

Study information

Scientific Title
Combined Laser Improves Scar Outcome (CLIPSO): A feasibility study assessing combined pulsed dye and fractional carbon dioxide laser on burn scar outcomes versus standard care

Acronym
CLIPSO

Study objectives
Combined pulsed dye laser and ablative fractional carbon dioxide laser treatment improves scar redness and pliability, reduces patient-reported scar-related distress and improves scar-related symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/08/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle, NE2 4NQ, United Kingdom; +44 207 104 8210; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0153

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Burns and corrosions of multiple and unspecified body regions

Interventions
Each participant will be randomised to one of three groups at first visit;
COMBINED LASER (CL) - 10 participants
SINGLE LASER (SL) - 10 participants
CONTROL (C) - 10 participants

A single scar site ≥1% TBSA is required for each patient. In the event that the patient has multiple or large areas of scar, an area ≥1% TBSA will be randomly identified and photographed for ongoing reference. The patient will be offered standard of care (pressure garments, AFCO2L) to the remaining scar areas as deemed appropriate by the reviewing clinician as is standard of care in the host institution.

INTERVENTION
All enrolled treatment arm participants (CL and SL groups) will receive laser under topical local anaesthetic due to the discomfort that may be associated with the treatment. This approach is already employed in the host institution, whereby all patients undergoing AFCO2L for small (<4% TBSA) areas are treated with topical LMX4 (4% lidocaine) cream for 60 minutes under occlusion prior to laser treatment. In the presence of multiple scars, eligible patients will be offered AFCO2L to these other areas if deemed appropriate by the PI, which may be delivered at the same time as
study treatment. The use of AFCO2L is standard care in the host institution for scar treatment. Patients will only undergo general or regional anaesthesia in the event that further scar burden elsewhere on the body is undergoing AFCO2L as per standard care in our unit; for low volume scars or where patients do not wish for laser treatment elsewhere on their body, topical anaesthesia will be chosen. No participants will receive general or regional anaesthesia solely for study participation.

COMBINED & SINGLE AFCO2 LASER (CL and SL) GROUPS
In the CL group, PDL therapy will always be delivered first using the 595nm VBeam Perfecta (Candela) with the
following settings:
- 10mm spot size (or proportionate to scar size and shape)
- 0.45 millisecond pulse duration
- Rate 1.5 Hz
- 5-7 Joule/cm2 fluence
- No overlap
- Single pass
- Dynamic cooling device 20/30 setting

The energy is selected to produce a degree of bruising during treatment without skin blanching. The skin response is instantaneous and should be dark purple to black. Whitening in the treatment area suggests over-treatment and is to be avoided. Once the desired response is observed, the entire trial scar should be treated.

AFCO2L therapy is delivered using the 10,600nm fractional CO2 Ultrapulse laser (Lumenis) with the following
settings:
- 35mJ – 50mJ micropulse energy
- Rate 300 Hz
- 5% density
- DeepFX setting
- No overlap
- Single pass

A cool compress will be applied for 20 minutes following laser completion to dissipate any residual heat. All laser will be administered by the study PI who has laser experience and training. Following laser delivery, paraffin ointment will be applied topically to all laser sites and dressed with non-adhesive silicone dressing. Patients are advised to remove these at home after

48 hours then apply paraffin ointment twice daily to all treated areas for two weeks. An aftercare leaflet is provided.
Participants are advised to avoid swimming for two weeks following laser. Following removal of dressings, all sites will be treated with standard scar treatments (pressure garment treatment, silicone, massage and moisturiser) by the scar therapy team.

The laser treatment will be delivered to intervention sites three times at six-week intervals. The time points for intervention have been determined based on a data from previous published research, as well as the clinical expertise of the PI who has conducted laser treatments and clinically evaluated individual response to therapy. All laser settings will be recorded for each visit. At subsequent visits, participants will be asked to report any adverse effects of the treatment and laser will be delivered using the previous settings.

STANDARD CARE FOR ALL GROUPS
All participants in the treatments and control arms will receive standard scar therapy, which may include scar moisturisation, massage, silicone and pressure garments dependent on scar quality. Standard scar care will be delivered by a senior scar therapist. To avoid patient inconvenience and excess appointments, study visits will be coordinated with scar therapy team to occur at the same time.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
595nm pulsed dye laser (PDL), 10,600nm ablative fractional carbon dioxide laser (AFCO2L)

Primary outcome(s)
1. Subjective scar assessment using Patient Observer Scar Score (POSAS) and Brisbane Burn Scar Impact Profile (BBSIP) at baseline, 4 months and 8 months.
2. Objective scar assessment using Manchester scar score, Patient Observer Scar Score (POSAS) and colorimetry at baseline, 4 months and 8 months.

Key secondary outcome(s))
1. Subjective itch assessment using Patient Observer Scar Score (POSAS) and Brisbane Burn Scar Impact Profile (BBSIP) at baseline, 4 months and 8 months.
2. Assessment of psychological scar impact using Patient Observer Scar Score (POSAS) and Brisbane Burn Scar Impact Profile (BBSIP) at baseline, 4 months and 8 months.

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Participants > 18 years of age
2. Hypertrophic burn scar > = 1% TBSA
3. Scars which would ordinarily be managed by pressure garments and laser intervention
4. All patients to be less than 3 months from burn injury at point of recruitment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Participants < 18 years of age
2. Pregnant or breast feeding females
3. Facial scars
4. Keloid scars
5. Hypertrophic scars of non-burn aetiology
6. Mature (pale) scars more than 18 months from time of injury
7. Inability to give informed consent
8. Systemic glucocorticoid use
9. Previous topical or intralesional steroid treatment to study scar
10. Fitzpatrick skin types 4 - 6
11. Non-English speaking

Date of first enrolment
01/10/2023

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository at Newcastle hospitals NHS Trust. In line with sponsor guidelines, all data will be stored for up to 5 years after the last visit is collected to allow adequate time for review, reappraisal or further research, and to allow any queries or concerns about the data, conduct or conclusions of the study to be resolved. Any paper documentation, including the master file will be archived in line with local procedures in secure storage provided off site. Access will be restricted by appropriate staff by locking the storage room. During the consent procedure participants will be informed of this. At the end of the research study, the data collected will be archived at Datatron; the Trust approved off-site archiving facility. The

retention period of 5 years is based upon NUTH guidance for non-Ctimp studies.
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Stored in non-publicly available repository, Published as a supplement to the results publication, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.6	04/01/2022	11/09/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.7	08/03/2023	11/09/2023	No	No