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Early laser treatment for burn scars

Submission date	Recruitment status	[X] Prospectively registered
10/06/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
14/06/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/11/2024	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English Summary
Background and study aims
Hypertrophic scars from burns injury affect about 120,000 people per year in the UK. These scars are red, thick, and firm. They can be tight, itchy and painful with the potential to reduce the ability to carry out everyday activities; such as eating, sleeping, or getting around. They can affect the self-esteem and body image of the patient. All of this impacts on return to work and quality of life, and can cause depression and psychosocial problems.

More people survive large burn injuries due to progress in both surgery and medicine. There are now more people that have to live with large, life-long scars. There is a definite clinical need to improve the treatment of these scars. Indeed the ambition statement of the national fundraising charity, Scar Free Foundation, is "to achieve scar-free healing within a generation".

The aim of this study is to test if treatment with pulsed dye laser leads to an improved outcome for the patient, both in terms of their quality of life and in the appearance or quality of their scar. It is thought that, if this laser treatment is given at an early stage of scar healing, the degree of scarring will be reduced by stopping these scars from forming. If laser treatment proves effective, not only will the outcome for the patient be improved but will mean a cost efficiency for the NHS. Additionally, this may lead to the development of new guidelines on laser treatment for scars globally.

Who can participate?
Patients with burn scars aged 16 years or older

What does the study involve?
Half the participants will receive standard care (care they would normally receive) for 6 months, while half will receive a course of three laser treatments, in addition to standard care. The participants will assess both their scar features and quality of life using simple questionnaires. Patient experience and cost-effectiveness will also be assessed and measured.

What are the possible benefits and risks of participating?
Other burn patients in the future may benefit.
Laser treatment has a number of associated adverse effects but these are usually well

prevented with judicious control of laser output parameters. The pain or discomfort of the laser treatment itself is minimised by the delivery of cold air during treatment and the option to take painkillers such as paracetamol prior to the treatment.

Where is the study run from?
Salisbury NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2021 to January 2024

Who is funding the study?
Research for Patient Benefit Programme by the National Institute for Healthcare Research (NIHR) (UK)

Who is the main contact?
Dr Mark Brewin, mark.brewin@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Mark Brewin

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283345

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 283345, CPMS 49143

Study information

Scientific Title
Early Laser for Burn Scars (EL4BS) - A multi-centre randomised, controlled trial of both the effectiveness and cost-effectiveness of the treatment of hypertrophic burn scars with Pulsed Dye Laser and standard care compared to standard care alone

Acronym
EL4BS

Study hypothesis
Early Pulsed Dye Laser treatment of hypertrophic scars improves both scar outcome and psychological impact for the burn patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2021. Bristol Research Ethics Committee Centre (Ground Floor, Temple Quay House, Bristol BS1 6PN, UK; +44 (0)207 104 8029; centralbristol.rec@hra.nhs.uk), ref: 21/SW /0049

Study design
Multicentre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Condition
Prevention/treatment of hypertrophic scars in burn patients

Interventions
Both arms of the trial will be given standard care. The choice of standard care for this trial includes; moisturisation and massage up to 2 - 3 times per day (as directed by the Health Care Professional; where maintenance of hydration is required) ± silicone gel treatment ± pressure garments, dependent upon scar maturation.

The control arm receives standard care only. The treatment arm receives a course of three Pulsed Dye Laser treatments at intervals of 6 weeks, in addition to standard care treatment. All follow-ups allow ± 1 week to allow for clinic administration.

Allocation will be determined using a validated password-protected, web-based system hosted by the UKCRC registered Clinical Trials Unit (ExeCTU). Randomisation ratio is 1:1 control to treatment and is stratified by study site. The system uses random permuted blocks of varying size, within strata with possible block sizes of 2, 4 or 6.

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient-rated Patient Observer Scar Assessment Scale (POSAS) at baseline and 6 months

Secondary outcome measures
Measured at baseline and 6 months
1. QoL: Bristol CARe scale.
2. Quality Adjusted Life Years (QALY): SF-12 Health Survey.
3. Scar colour: Colorimeter measurements of redness (DSMIII ColorMeter, Cortex Technology, Denmark). Objective measurement is compared to POSAS colour score.
4. MCID - A 7-point scale question evaluates improvement at 6 month follow-up, as judged by the participant.

Overall study start date
21/05/2021

Overall study end date
10/01/2024

Eligibility

Participant inclusion criteria
1. NHS patients, with burn injuries >1% Total Body Surface Area (TBSA), are eligible if they have had skin grafts to,
or have conservatively managed, burn wounds or donor sites that:
1.1. Have delayed healing of greater than 2 weeks.
1.2. Have potential for Hypertrophic Scarring (HS).
1.3 Are suitable for scar management therapy.
2. The scar is within 3 months of healing, where healing time-point is defined during wound management. The combination of excessive redness with increased thickness and/or hardness provides clear indication of HS.
3. Children aged 16 - 18 are able to participate with appropriate consent.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
150

Total final enrolment
153

Participant exclusion criteria
1. Unable to give informed consent.
2. Below 16 years of age.
3. Prone to keloid scarring.

Recruitment start date
13/09/2021

Recruitment end date
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury District Hospital
Salisbury NHS Foundation Trust
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
369 Fulham Rd
Chelsea
London
United Kingdom
SW10 9NH

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Mid and South Essex NHS Foundation Trust
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Freeman Hospital
Newcastle Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
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L35 5DR

Sponsor information

Organisation
Salisbury NHS Foundation Trust

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Odstock Road
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United Kingdom
SP2 8BJ
+44 (0)1722 425027
lbell1@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.salisbury.nhs.uk/

ROR
https://ror.org/00ja2ye75

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Firstly, the trial protocol will be published in conjunction with the commencement of the trial in a journal such as BMJ Open. Results from this study will be disseminated to HCPs through both publications in the journal Burns and presentations at British Burns Association (BBA), European Burns Association (EBA) and/or International Society of Burn Injury (ISBI) annual meetings. The main publication will be submitted to Burns Open and this is costed in the budget. The qualitative component of the RCT is published within a high impact journal such as BMC(Open).

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. RedCap at Exeter University. All investigators and trial site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Personal data will be stored on Consent Forms at sites and will remain at sites. Once consented into the study participants will be assigned a trial ID. The trial ID will be used to identify data collected on CRFs and stored on the CTU database. Access to the CTU database is password protected and limited to those individuals necessary for quality control, audit, and analysis. The sponsor will act as the data controller for this study and will archive identifiable information for up to 5 years after the study has finished.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v14	21/05/2021	14/06/2021	No	Yes
Protocol article		18/01/2022	04/08/2022	Yes	No
Statistical Analysis Plan	version 1.6		08/06/2023	No	No
HRA research summary			28/06/2023	No	No
Plain English results			28/11/2024	No	Yes