

# Early laser treatment for burn scars

<b>Submission date</b> 10/06/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2025	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### 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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**Contact details**

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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 objectives

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

## Health condition(s) or problem(s) studied

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  $\pm 1$  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

### **Completion date**

10/01/2024

## **Eligibility**

### **Key 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

**Key exclusion criteria**

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

**Date of first enrolment**

13/09/2021

**Date of final enrolment**

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  
United Kingdom  
L35 5DR

# Sponsor information

## Organisation

Salisbury NHS Foundation Trust

## Sponsor details

Odstock Road  
Salisbury  
England  
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-publicly 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?
<a href="#">Participant information sheet</a>	version v14	21/05/2021	14/06/2021	No	Yes
<a href="#">Protocol article</a>		18/01/2022	04/08/2022	Yes	No
<a href="#">Statistical Analysis Plan</a>	version 1.6		08/06/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			28/11/2024	No	Yes
<a href="#">Results article</a>		17/04/2025	08/05/2025	Yes	No