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Light treatment for scleroderma finger ulcers - study 2

Submission date
14/05/2025

Recruitment status
Recruiting

Registration date
29/05/2025

Overall study status
Ongoing

Last Edited
19/05/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims:
Scleroderma (otherwise known as Systemic Sclerosis) is a disease that affects the skin and internal organs of the body, including the blood vessels. Damage to the blood vessels can result in poorer blood circulation, increases the risk of developing finger ulcers. Finger ulcers are common in patients with scleroderma and many of the currently used treatments can often cause side effects or are not effective. The research team wish to investigate a new, light-based therapy, to potentially treat finger ulcers in the future. In a previous study conducted by the research team, the custom-built light-based treatment device, consisting of red, infrared, and violet light was found to be safe and easy to use. There were also some early signs of potential benefit for finger ulcers in patients with scleroderma. To take this treatment approach forward, the research team now need to find out what is the best 'dose' of light to use.

Who can participate?
Patients with a confirmed diagnosis of systemic sclerosis (often referred to as 'scleroderma'), who are 18 years of age or older and who attend Salford Royal Hospital for their care can take part in this study.

What does the study involve?
Participants will need to attend Salford Royal Hospital for three study visits. Visits will take place in the morning, ideally over 3 consecutive days. However, if this is not possible, the visits can be spaced out to a maximum of 3 days between each visit. Study visits will last approximately 2 hours.
Participants will receive one of three possible 'doses' of the light therapy at each of their study visits. These doses are measure in units of energy called Joules and participants will receive doses at 5, 10 or 20 Joules/cm^2 during the course of the study.
Researchers are not expecting any treatment benefit from these single doses of light but want to understand how the skin (blood flow and temperature) reacts to increasing doses of light. All participants will receive the three 'doses' of light over the course of their study visits (but not all in the same order) and there is no dummy (placebo) treatment.
At the first study visit, participants will be asked questions about their medical history and any medications they are taking, and this information will be noted by the research team. They will have their hands and fingers examined for any skin thickness changes, using a skin pinch

technique called the ‘modified Rodnan skin score’, which is used by clinicians routinely to assess scleroderma. In addition, participants will have their skin thickness measured using an ultrasound machine (radiation free, painless). This will involve the research team applying a sterile ultrasound gel to the surface of the participants skin (on their hands and fingers) and using the probe to take pictures that will show the thickness of their skin.

At each of the study visits, the research team will examine participants fingers for any changes (such as for any new ulcers, although this is not expected from the light therapy).
They will measure the blood flow through participants hands using a laser Doppler device and the temperature of the hands using a thermography camera. These measurements will be taken immediately before the light treatment and then directly after, and then every 10 minutes for 90 minutes. This is to see if low level light treatment can improve the flow of blood to the skin and what is the optimum dose to potentially treat finger ulcers in the future.

What are the possible benefits and risks of participating?
The study will not have any direct benefits for participants, but it will help researchers in their understanding of scleroderma. There will be no immediate benefit for participants from these three single light applications to their skin. The purpose of the study is to examine changes in blood flow and temperature of the hands due to the different ‘doses’ of light. This work will help the researchers understand how light interacts with the skin and may lead to further studies exploring light-based treatment for scleroderma finger ulcers.

The possible risks are unknown but not expected. In previous study of light treatment for scleroderma finger ulcers there were no significant side effects seen. Furthermore, in other studies using light treatment in other types of ulcers (e.g. in patients with diabetes) there have been no significant side effects. Any discomfort (if any at all) from the application of the ultrasound machine gently touching participant’s skin will be minimal. The research team will wear gloves and use a special cover over the ultrasound machine to reduce the possibility of infection.

Where is the study run from?
The study is led by Dr Michael Hughes – Clinical Senior Lecturer & Honorary Consultant Rheumatologist. The study will be run by the Scleroderma Research Group at Salford Royal Hospital - Northern Care Alliance NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2024 to February 2026

Who is funding the study?
The study will be funded from the Chief Investigator’s PI account, which has sufficient funding to cover study costs, including the custom-built light-based treatment device and participants travel expenses. The PI account is with Dr Michael Hughes and is held by Salford Royal Hospital, Northern Care Alliance NHS Foundation Trust (UK).

Who is the main contact?
Mr Paul New (study co-ordinator):
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
351238

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A physiological study to optimise a novel low-level light treatment for digital ischaemia in patients with systemic sclerosis

Acronym
DULight2

Study objectives
Principal research question: To assess the safety, tolerability, and efficacy of the Low Level Light Treatment (LLLT) device in patients with Systemic Sclerosis (SSc) and to determine the optimal dose of light required.

Secondary research questions: To investigate potential factors that may effect the outcome of LLLT device on patients with SSc including age, disease duration and skin thickness.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/03/2025, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 25/NW/0044

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Systemic sclerosis (SSc), otherwise referred to as scleroderma

Interventions
This is a clinical trial to study a novel intervention that will investigate the effectiveness and safety of Low Level Light Therapy (LLLT) in patients with systemic sclerosis (SSc).

Patient recruitment:
Twenty patients > 18 years of age with SSc-spectrum disorders will be recruited from Salford Royal Hospital.

Study visits protocol:
Prior to the initial study visit, an independent member of the study team shall perform the randomisation procedure. Randomisation will be done in-house by the study team (using a random number generator/Excel, etc). All patients shall receive combined sequential red (810nm)/infrared (850nm) followed by blue (410nm) wavelengths. The dose per visit shall be

dose-escalated in a pre-determined randomised order over the course of the three study visits: 5 J/cm², 10 J/cm², and 20 J/cm². Participants will be randomised before their first study visit by a member of the research team using an excel random number generator to complete the task.

Study visits will be conducted in a temperature-controlled (at 23°C) laboratory at Salford Royal Hospital. Patients will attend a total of 3 study (morning) visits over 3 (ideally consecutive) days. The minimum time between study visits is 1 day, and the maximum time between study visits shall be 3 days.

Relevant patient- and disease-related demographics and characteristics shall be collected. At each study visit, any relevant change/s to the current drug treatment will be documented.

Preparation:
Patients will be asked to abstain from caffeine-containing drinks and smoking for at least 4 hours prior to the study.

Application of the LLLT device:
We will apply the LLLT (for all study visits) to the dominant hand unless there are specific reasons not to. Both the patient and device operator/s will wear appropriate safety goggles at all times whilst the LLLT device is in operation. The patient will place their hand within the treatment area of the light-based device. The device will be directly controlled by an attached custom-built computer interface. The dose will be delivered either at 5 J/cm², 10 J/cm² or 20 J /cm² based upon the patient study visit sequence/randomisation. The LLLT will take approximately 10-15 minutes to complete.

Laser Doppler imaging (LDI)
LDI, which measures blood flow, allows a perfusion map (in arbitrary units) to be produced of the studied area. We will perform LDI immediately before and after the light exposures and then every 10 minutes for 90 minutes. LDI will include all the digits (thumb and four fingers) and dorsum of both the treated and untreated hands. Bilateral (matching) standard regions of interest (ROI) shall be assessed on the treated and untreated hands at all LDI time points. The rationale of imaging these sites is to demonstrate an objective localised increase in skin perfusion with light treatment, and whether this differs between the digits and dorsum of the hand.

Thermography
Thermographic assessment measures skin temperature and provides an indirect measure of small and large blood vessel function, and can also be applied to scleroderma-DUs. Standardised thermographic images shall be acquired immediately before and after the light exposures, and then every 10 minutes for 90 minutes. As for LDI, thermography, we will simultaneously image the whole treated hand to capture the fingers and dorsal aspect, and with contralateral counterparts on the untreated hand.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Safety will be measured using medical data documenting safety issues at each study visit and between visits (e.g., new concerns about cutaneous changes, pain etc.) at one timepoint
2. Tolerability will be measured using patient-reported pain on a Visual Analog Scale (VAS) (0-100, where 100 is the most severe pain imaginable by the patient) directly attributed to the LLLT will be recorded immediately after treatment, to assess

tolerability, at each study visit.
3. Efficacy will be measured using laser Doppler imaging (LDI) immediately before and after the light exposures and then every 10 minutes for 90 minutes
4. Skin temperature which provides an indirect measure of small and large blood vessel function, will be measured using thermography immediately before and after the light exposures, and then every 10 minutes for 90 minutes

Secondary outcome measures
Assessment of persistent cutaneous digital ischaemia:
Taken from the hand original acquired LDI and thermography images (as above), for any digital (finger) ulcers (DU) or pitting scars (DPS) present, perfusion measurements will be assessed at the lesion center (DU/DPS 'core') and immediately adjacent tissue (DU/DPS 'periphery').

Assessment of digital skin fibrosis:
The extent/severity of the finger (digital) skin sclerosis on the treated hand shall be assessed:
1. By a trained assessor using the modified Rodnan skin score by manual palpation (0-3 score, where 0 is normal and 3 is severe skin fibrosis/sclerosis).
2. High frequency ultrasound (HFUS) to measures skin thickness of the hands and finger

Overall study start date
01/08/2024

Completion date
20/02/2026

Eligibility

Key inclusion criteria
1. Clinician confirmed diagnosis of SSc-spectrum disorder.
2. Eighteen years of age or older at the time of recruitment
3. Able to give full informed consent
4. Steady dose (for at least two weeks) of relevant prescribed drug (e.g., vasodilatory and vasoactive) therapies for SSc-associated vasculopathy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Patients receiving treatment with intravenous vasodilatory/vasoactive therapy (e.g., iloprost)
2. Finger Digital ulcers currently requiring hospital admission (e.g., to receive iloprost) or awaiting surgery for digital vasculopathy
3. Currently receiving phototherapy for clinical reasons (e.g. ultraviolet-B therapy)

Date of first enrolment
12/05/2025

Date of final enrolment
20/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Care Alliance NHS Foundation Trust
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Sponsor type
Hospital/treatment centre

Website

https://www.northerncarealliance.nhs.uk/

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
20/02/2027

Individual participant data (IPD) sharing plan
Data sharing statement to be made available at a later date

IPD sharing plan summary
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 4	26/02/2025	19/05/2025	No	Yes
Protocol file	version 4	26/02/2025	19/05/2025	No	No