Participant Information Sheet

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

Short Title: Light treatment for scleroderma finger ulcers - study 2

Principal Investigator: Dr Michael Hughes

1. Introduction

You are being invited to take part in a study based at Salford Royal Hospital. Before you decide it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

2. Why have I been invited to take part?

You are being invited to take part in this study because you are a patient with scleroderma.

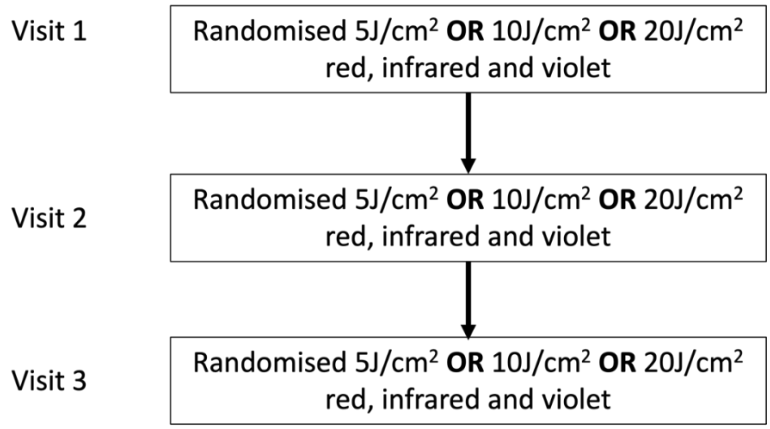
3. What is the purpose of the research?

Finger ulcers are common in patients with scleroderma and many of the currently used treatments can often cause side effects or are not effective. We want to investigate a new, light-based therapy to potentially treat finger ulcers in the future. In our previous study, our 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, we now need to find out what is the best ‘dose’ of light to use.

4. What will happen if I take part?

If you wish to take part in this study, you 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, we can allow up to a maximum of 3 days between each study visit. Study visits will last approximately 2 hours.

At each visit you will receive one of three possible ‘doses’ of the light therapy. This is summarised in the chart below. We 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 patients will receive the three ‘doses’ of light over the three study visits (but not all in the same order), and there is no placebo ‘sham’ treatment.



Initially, one of the research team members will ask some questions about your medical history and your medications. The light therapy will take about 15 minutes to perform..

At each visit we will examine your fingers for any changes (such as for any new ulcers, although this is not expected from the light therapy). At the first visit we will examine your fingers and the backs of your hands for any skin thickness changes, as is done routinely in the Scleroderma outpatient clinic. In addition, we shall measure the thickness of your skin at these sites using an ultrasound machine. This will involve applying a sterile ultrasound gel to the surface of your skin and using the probe to take pictures that will show us the thickness of your skin.

We will measure the blood flow through your 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.

5. Do I have to take part?

No, taking part is voluntary and it is up to you to decide whether or not to take part. Any help you give is very much appreciated. If you decide to take part, you are free to withdraw at any time without giving a reason. A decision to withdraw at any time will not affect the standard of any care you receive. If you do wish to withdraw, simply inform a member of the research team and they will cancel any planned future visits. Images and data collected up to the point of withdrawal will be retained by the research team for use in the study. If you decide not to take part, you do not have to give a reason.

6. What are the possible benefits of taking part?

The study may not have a direct benefit to you, but it will help our understanding of scleroderma. We expect no immediate benefit from these three single light applications to your skin. The purpose of our study is to examine changes in blood flow and temperature of the hands due to the different ‘doses’ of light. This work will help us to understand how light may interact with the skin and may lead to further studies exploring light-based treatment for scleroderma finger ulcers.

7. What are the possible disadvantages and risks of taking part?

The possible risks are unknown but not expected. In our 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 the skin would be minimal. We will wear gloves and use a special cover over the ultrasound machine to reduce the possibility of infection.

8. *a)* How will we use information about you?

We will need to use information from you and your medical for this research project.

This information will include your

- Name
- Gender
- Age
- Hospital number
- Address
- Telephone number

People will use this information to do the research, to check your records to make sure that the research is being done properly and to understand which patient groups are participating in research.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Northern Care Alliance NHS Foundation Trust is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 5 years. The study data will then be fully anonymized and securely archived or destroyed.

8. *b)* What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

8. *c)* Where can you find out more about how your information is used?

You can find out more about how we use your information,

a) at www.hra.nhs.uk/patientdataandresearch
b) our leaflet available from https://www.ncaresearch.org.uk/patients-public/
c) by asking one of the research team
d) by sending an email or ringing us (details below)
e) by contacting the Northern Care Alliance NHS Foundation Trust Data Protection Officer DataProtection.Officer@nca.nhs.uk
f) by viewing the Sponsor's privacy link NCA_Privacy_Notice_Final_Version_1.5.pdf (northerncarealliance.nhs.uk)

9. Expenses and payments?

We are unable to pay you for participating in this study. However, transport to and from visits may be arranged for you if you have difficulty travelling to appointments. We will be happy to reimburse you reasonable travelling expenses for each of your study visits

10. What will happen to the results of the research study?

The final outcomes from the study will be communicated by presentations at scientific meetings and by publications in scientific journals. Unless specifically requested, you will not be informed of the results, as this is an imaging study and will not change your clinical management. However, you will be told how to access the final publication upon request. We will aim to publish the results approximately 12 months after completion of the study

11. Who is organising the research?

The research is organised by Dr Michael Hughes, Senior Clinical Lecturer and Consultant Rheumatologist, from the University of Manchester. The Northern Care Alliance NHS Foundation Trust is the sponsor of the study.

12. Who has reviewed this study?

We can confirm that the study has been reviewed and approved by an appropriate NHS Research Ethics Committee, (North West - Greater Manchester South Research Ethics Committee).

13. What if there is a problem?

If taking part in the study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action for compensation against Northern Care Alliance NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Regardless of this, if you have a concern about any aspect of the way you have been approached or treated during this study, you should speak to the researchers who will do their best to answer your questions (see contact details below).

If you have any complaints about the treatment you have received as part of this study, you can contact the hospital PALs (Patient Advise and Liaison Services) team:

Patient Advice and Liaison Service
Unit 7-8 Whitney Court Hamilton Street
Southlink Business Park Oldham
OL4 1DB
Telephone: 0161 778 5665
Email**:** pals@nca.nhs.uk

Contact Names and Details for Further Information

If you have any questions about this research, please write to us or call us on 0161 206 4295 Thank you for taking the time to read this information sheet.

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Study Coordinator - Mr Paul New
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Thank you for taking the time to read this participant information sheet. Please do not hesitate to contact the study team as above for any further information or if you have any questions