EL4BS

EARLY LASER FOR BURNS SCARS

PATIENT INFORMATION SHEET

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.

What do these words mean?

- “Multi-centre” means this study is running at seven NHS hospitals in England.
- “Randomised” means that those who take part will be randomly put into one of two study groups.
- “Controlled” means that, as well as a treatment group, there is control group who do not get laser treatment during the study.
- “Effectiveness” is the measure of any treatment effect.
- “Cost-effectiveness” is the measure of value for money of any treatment.
- “Hypertrophic” defines scars that are red, raised and firm.
- “Pulsed dye laser” is a safe type of medical laser with a beam of yellow light that is used to treat red skin conditions.
- “Standard care” is the routine care offered by the NHS for burn scars

Contents

1 Why we are doing this study

We would like to invite you to take part in our study. Before you decide if you want to take part, we would like you to understand why we are doing this study. Also, this sheet will explain what would be involved, if you agree to take part.

Reading this information sheet should take about 30 minutes. Our team can go through this with you, if you need. At any stage, please ask us if anything is unclear or if you would like more information.

Taking part in the study is *voluntary.* It is up to you to decide if you would like to take part. Whether you take part, or not, will not affect the care for your burns. You do not have to decide today. Other people can help you make your decision. This could be your family, friends or GP. The Patient Advice and Liaison Service at your hospital can also help you (contact details below). If you have any questions after you leave, you can call us on [insert phone number].

- Part **one** tells you the aim of this study. It also explains what will happen if you take part.
- Part **two** gives you more information about how the study will run.

2 Part one

What is the aim of the study?

2.1 A burn injury can lead to 'hypertrophic' scarring. This can affect up to 70% of burns patients. Such scars can be life-changing. They can be itchy, painful and tight. These issues can affect every part of your life; from work to sleep, hobbies to exercise. In turn, they can affect your mental health and quality of life.

Worldwide, the current treatment of this scarring includes moisturisation with creams, use of silicone gels, wearing pressure garments and massage. 'Pulsed Dye Laser' (PDL) treatment is also widely used. There is evidence that PDL can reduce the redness of scars, soften them and reduce symptoms such as itch.

2.2 However there are gaps in the evidence that we now want to answer. We do not know if we should treat soon after a burn heals or leave it until later. Normally, we wait at least six months. This study aims to tell us if PDL does improve these scars and in what way. It will also tell us if giving it earlier – within three months – is better or no different than what we do currently.

Why have I been invited to participate?

2.3 You have been invited to join our study because you have had a burn injury. You may now have signs of 'hypertrophic' scarring, or you are at risk of developing this scarring. In other words, you have scarring which may benefit from scar treatment.

How long is this study?

This study is for a total of 6 months. For treatment of this scarring, you would normally be in our care for at least 6 months. This study is unlikely to mean extra hospital visits for you. Your study visits would be at intervals when you would expect your normal care.

What will happen to me if I take part?

If you decide that you would like to take part, a member of the study team involved in your scar care will explain the study to you. They will answer any questions that you might have. They will ask you some questions about your health and any medications you might be taking. You will then be asked to sign a consent form to agree to be part of the study. You should only do this if you are happy that you understand the study and want to take part.

2.4

If you consent to participate, you will be *randomly allocated* to either:

- standard care for your scars (for example, moisturisation and massage, pressure garments and topical silicone)
- standard care **and** laser treatment

This 'randomisation' means that there is a 50:50 chance (the same as tossing a coin) that you are chosen to join either group. This random choice is very important. To establish whether laser works, we need a group of patients with similar scars who do not have early laser treatment. There needs to be this comparison (or control) to see if early treatment makes a difference.

If you are randomly selected to be in the laser treatment group, you will start to receive early laser treatments for your scar, as well as your standard care. By early, we mean within three months of your burn healing. Usually, laser treatment is not given until at least six months after your burns have healed.

After the first laser treatment, you have a further two treatments. These will be at four weeks and eight weeks after the first treatment. Each laser treatment is undertaken in the outpatient clinic and takes around 20 minutes. Additionally, there will be a short period of time before each treatment when your scar is assessed as described below. You do not need to stay in hospital.

If you are randomly selected to be in the non-laser treatment group, which is also known as the 'control' group, you will be asked to attend for three standard care appointments. These will have identical timings to the laser treatment group. These will not be wasted appointments. Your scars will be assessed in the same way as the laser treatment group. You will also be given all the standard scar treatments, as needed. Importantly, if your scar still needs laser treatment by the end of the study, it will then be offered to you when we would normally do this. This would be at around six months after your burn has healed.

2.3

How do we assess the scarring?

There will be four appointments in total at the hospital. At each appointment, you will get expert assessment, advice and/or treatment for your scarring. It is vital that you and your scar are assessed to establish whether the laser treatment makes a difference. This can take up to 30 minutes.

At every visit we will photograph your scar. They will ensure we look at the same area each time you come back. These photos will be taken by the healthcare professional involved in the management of your scar. They will be used in the data analysis and then kept in the medical records after the study ends as part of standard scar care. We will only use them in reports with your consent. We will ask seven questions about what you think about the scar. These questions ask you to rate symptoms and appearance on a scale of 1 to 10. We will also assess the scar using a similar scale.

At the first and last appointment, we will assess you in more detail. As well as photographs and the scar scales, we will ask you to complete two other questionnaires. These will assess how your scar has affected other things such as your quality of life. You will be asked some questions about the financial impact of living with your scars. Finally, we will use a harmless research device called a 'colorimeter' to measure the colour of your scar. Colour is important as it is a reflection of any remaining activity within your scar and makes it more visible.

The total **study** time over 6 months is approximately 2 hours. This would be the time in addition to your normal scar care appointments. Given your scarring, if you are in the study, your hospital visits will have the same timings as the visits you would normally have made to treat your burns.

What happens after the study ends?

2.6 After the study ends, patients in the non-laser treatment group will be offered laser treatment. Patients in the laser treatment group will be offered further laser treatment if we think it may still be beneficial. All patients will be offered further scar care if it is needed.

If I agree to take part, can I attend just some of the appointments?

2.7 If you agree to take part and plan to complete the study, it is important that you attend all the appointments and to carry out all the recommended treatments to the best of your ability. This makes it much more likely that the study will find reliable answers to the study questions. Appointments are going to be a little longer and possibly involve laser treatments.

Will it cost me anything? Can I claim expenses?

2.8 It is expected that you will not be required to make any additional visits to the hospital in order to take part in this study. All hospital visits will be at times when you would normally have appointments for your burn injury. However, you will be able to claim travel expenses for attending any additional hospital visits for the purpose of this study. You will not receive any payments or fees for being involved in the study; however you are not expected to pay for any treatments during the study.

2.9 What alternative treatments are available?

Whether you agree to participate in the study, or not, you will continue to get standard care for you scar. This includes moisturisation, massage, silicone and pressure garments.

2.10 What are the possible benefits of taking part?

We are unable to guarantee any direct benefit to participants that take part in this study. You will be receiving standard care for your scars no matter which group you are in. Your scars will also be regularly assessed by our expert study team. You will be contributing to an improvement in scar treatment for future patients. In particular, we may learn whether earlier laser treatment of scars is beneficial or not. The information gained will also help future studies.

What are the possible disadvantages or risks of taking part?

The sensation of laser treatment is like being flicked by an elastic band. It is not very painful. It feels warm and leads to bruising. Bruising is an expected and necessary feature of the treatment. It shows that the laser has worked. Other side effects may include redness, some discomfort or swelling. Occasionally, 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.

There are few side effects for any “standard care” treatment such as regular massage and moisturisation. They can include a rash, irritation or discomfort. Usually, they resolve when the treatment stops.

Laser treatment may be less effective for patients with darker skin types. There is also an increased risk of permanent changes to skin colour. Laser settings will be adjusted to reduce this risk.

It is appreciated that any treatment, including laser, may not improve your scarring. If you have any problems or queries between visits, then you can contact using the contact details at the end of this information leaflet.

Is there any further commitment to the study?

2.12 Twenty participants from the study will be contacted for a telephone interview. The interview will last approximately for 45 - 60 minutes. It will be carried out by a research nurse with expertise in carrying out interviews. Interviews will be audio-recorded to ensure that we have accurate details of what participants share and say. These audio recording will be destroyed once the data has been transcribed, or written down by the research nurse. No identifiable data will be collected in these interviews. Data will be stored securely; hard copy data will be kept in a locked drawer in a locked office at Bournemouth University and electronic data stored on a BU password protected computer.

The interview is seeking to understand your experience of the treatment. It will also assess the impact that either this treatment or your burn has had on your social and psychological wellbeing. It will explore how the treatment made you feel and any perceptions of the treatment by their loved ones or carers, where appropriate. There are no right or wrong answers. Following this there will be clarification of the treatment you experienced such as Pulsed Dye Laser or moisturisation/massage, and/or silicone gel treatment and/or pressure garments. We will ask your consent to be contacted for this telephone interview and for your contact details to be shared with the researcher for this purpose only. This part of the study is voluntary and you do not have to take part. The study team may also want to follow your progress as your scarring continues to mature. We will ask your permission to contact you in the additional consent form.

3 Part two

3.1 What if new information becomes available about the treatment?

Sometimes we get new information about the treatment being studied. We will tell you and your doctor about it and give you an opportunity to discuss it with a study nurse or doctor. If this new information means that we should stop the study, or change how we are running it, we will do this. We will make sure that you continue to be offered the best treatment for your type of scarring.

3.2 What will happen if I don't want to carry on with the study?

If you agree to participate in the study, it is important that you attend all four appointments. However, you are free to withdraw from the study at any time. You do not have to give a reason for withdrawing. Whatever you decide, it will not change the care that you receive. You can either withdraw completely or choose to keep in contact with us to let us know your progress. Information collected earlier in the study may still be used to help us with our results.

3.3 What if there is a problem?

If you have concerns about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions (contact details below). It is highly unlikely that anything will go wrong, but if you are harmed by taking part in this research, you should understand that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (insert Local PI contact details here). If you remain unhappy and wish to complain formally you can contact your local Patient Advice and Liaison Services (PALS) group or local equivalent group (insert name where applicable) (insert contact details here).

Why are you assessing my quality of life?

It is very important for us to understand the effect of your scar(s) and treatment on your quality of life. This means that we can provide future patients with information on what they can expect to experience.

3.4 How do I give permission to participate?

If you agree to take part, we will ask you to sign a consent form after we have confirmed that you understand the nature of the study, its benefits and risks. Any person over 16 years old is allowed to participate in a clinical trial and may be included in this study if they meet the criteria for inclusion.

How will we use information about you?

We will need to use information from you or from your medical records for this research project. This information will include your patient code that will be given to you at the start of the study. People will use this information to do the research or to check your records to make sure that the research is being done properly.

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 the patient code number instead. 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.

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. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital/ your GP. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

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

- at www.hra.nhs.uk/information-about-patients
- at www.salisbury.nhs.uk/about-us/your-patient-information-privacy-notice/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the Data Protection Officer; Heidi Doubtfire-Lynn at: sft.information.governance@nhs.net
- by ringing us on 01722 425119

Will my General Practitioner/Family Doctor (GP) be involved?

You will be asked to give permission for us to tell your GP about your involvement in the study. This is good practice for your care. You are free to choose to withhold your permission.

What will happen to the results of the research study?

3.10 The results will be published in medical journals or presented at medical conferences. All the information that we present will continue to be anonymous. If you wish to be informed of the results of the study, please inform the research staff. We can ensure that this happens at the end of the study once all the information has been processed.

Who is organising and funding the research?

3.11 The Study Sponsor, or main site, is Salisbury NHS Foundation Trust. The study is being coordinated by the University of Exeter Clinical Trials Unit. It is funded by the National Institute for Health Research's Research for Patient Benefit Programme. NHS Resolution Indemnity insurance applies for the design and carrying out of this study. Bournemouth University holds Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University. Bournemouth University holds Professional Indemnity insurance to cover the legal liability of the University as Research Sponsor for harm to participants arising from the design of the research.

Who has reviewed the study?

3.12 All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by a central ethics committee and the local committee relevant to your hospital. Additionally, several other committees monitor the set-up and progress of the study. This includes a data monitoring committee, a patient advisory group and a trial steering committee.

3.13 Further information and contact details

If you require any further information, please contact the research team on the details below. If you would prefer to speak to an independent person regarding the study, please contact the Patients Advice and Liaison Service (PALS) on (name/telephone number)

If you need to contact your research team at any stage, these are their names and details:

- Principal Investigator (name/telephone number)
- Research Nurse (name/telephone number)
- Scar Management Therapist (name/telephone number)
- Patient Advice and Liaison Service (name/telephone number)

Thank you for taking time to read this patient information sheet