A study investigating the effect of combined laser treatment on burn scars (CLIPSO Study)

PARTICIPANT INFORMATION SHEET

Investigators: Mr. Christopher Lewis & Dr. Emma Hodgkinson

We would like to invite you to take part in a research study investigating the effect of laser treatment on burn scars. Before you decide whether to take part it is important that you understand what the research involves and why it is being done. This information sheet provides details about the study; take your time to decide whether or not you wish to take part.

This study is being undertaken as research at the Northern Regional Burn Centre and is funded by the Royal College of Surgeons of England and the Blond McIndoe Research Foundation.

- **Background**

After a burn, some peoples' scars may become thick, raised and lumpy after the wound heals. This is called a **hypertrophic scar** and affects up to 6 out of 10 patients who suffer a burn injury. This can happen if you have an operation to treat your burn or if it heals with dressings. These scars are red and firm and can affect a patient's physical and mental health, causing itch, dryness, pain and problems with joint movement due to stiffness.

Laser is a relatively new way of treating burn scars. We need more scientific evidence to see whether laser is useful to treat burn scars. This study will combine two different lasers (pulsed dye laser and carbon dioxide laser) commonly used to treat scars to see whether they work better together and improve the way that you feel the scar looks. The combination laser will be compared to a single laser we already use (carbon dioxide laser) or no laser treatment.

The pulsed dye laser is designed to treat blood vessels and redness in your scar. The light heats tiny blood vessels in your scar which give it the red colour and damages them, causing bruising. This is a normal reaction to this type of laser and the research team are looking for this.

The carbon dioxide laser creates microscopic shallow holes in your scar, which help them to mature and can improve feelings of tightness. Fractional laser can also make scars softer / flatter.
We want to see whether any symptoms caused by your scar that you experience (for example, itch), get better with the laser treatment. Your scar will be assessed by the research team to see how it changes with laser treatment.

- **Why have I been chosen?**

You have been chosen because you have had a burn to your skin needing specialist burn care at the Northern Regional Burn Centre in Newcastle. You have been invited as your scars are hypertrophic or your doctor feels that you may develop hypertrophic scars in the future.

- **Do I have to take part?**

No, it is entirely your decision whether you choose to take part of not. If you decide to take part then change your mind, you are free to withdraw at any time and without giving a reason. If you do not wish to take part, this will have no effect on your care now or in the future. You are free to withdraw from the study at any time without giving any reason. 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.

- **What will the study involve?**

Study visits are likely to be at the same time as your usual appointments with the scar therapy team that you would attend if you were not taking part in this study. If you are chosen to receive the laser treatment, you will be invited to attend three additional appointments to receive this treatment.

If you agree to take part in this study, a member of the study team will explain the study to you. You will then be asked to sign a consent form. You should only do this if you are happy that you understand the study and want to take part. It is up to you to decide to join the study. If you are unable to sign the consent form due to a physical

disability or impairment, a witness can sign this for you on your behalf. Your GP will be informed of your involvement in the study with your consent.

Once the consent form is completed, you will be randomly selected into one of three groups.

- One group will receive standard care only (moisturiser, massage, pressure garments or silicone)
- One group will receive standard care **and** single laser treatment (carbon dioxide laser).
- One group will receive standard care **and** combined laser treatment (pulsed dye laser and carbon dioxide laser)

Neither you nor the study team can choose which treatment group you will be in – it is randomly chosen. Whichever group you are in, you will receive scar therapy from the burns scar team (for example, advice on massage, moisturisation, silicone, compression garments).

1. Standard care control group

The control group will attend for 3 standard care appointments in an outpatient clinic. This will be at regular intervals of 4 months, and each appointment will take around 30 minutes. During your appointment, you will be seen by members of the scar therapy team and research team to assess your progress. Photographs will be taken of your scar and you will be asked to complete two short questionnaires about how you feel your scar looks and affects you on a day to day basis. A member of the research team will examine your scar. This may involve touching the scar but should not hurt.

Participants in this group may still be eligible for laser treatment at the end of the study. Once the research is complete, your doctor will examine your scars to assess whether you will benefit from laser treatment. If you are in this group and are interested in laser treatment at the end of the study, please speak to your doctor or a member of the research team.

2. Treatment single and combined laser groups

The single and combined laser groups will attend hospital for 3 laser treatments, in addition to standard care appointments. There is a gap of 6 weeks between treatments. Laser treatment is done in the laser suite near to the plastic surgery department. At each appointment, photographs will be taken of your scar and then an anaesthetic numbing cream will be applied to your scar for 60 minutes before the laser treatment. You can go for a drink or food in the hospital while the numbing cream takes effect.

Before the procedure, the cream will be removed and your skin cleaned. A member of the laser team will perform your treatment. You will be given laser eye protection goggles to wear as the laser light is very bright. The laser treatment is not usually painful however you may find it uncomfortable. Once complete, a cool pack will be put on your skin, which helps relieve any discomfort. Vaseline ointment will be applied to your scar together with a non-stick dressing. Each appointment will last around 90 minutes total after which you can go home.

The local anaesthetic effect will wear off after a few hours. You may find the area sore after treatment, but simple painkillers like paracetamol or ibuprofen can be taken to help with the discomfort.

You can remove the dressings yourself at home 2 days after your laser treatment. The area can then be showered as normal. You will be given a tube of Vaseline ointment. Once you have removed the dressings, apply a small amount of the ointment to the treated area(s) twice a day. Please do this for two weeks only.

If you are using pressure garments, you can restart wearing these after the dressings have been removed. Please keep the treated area(s) protected from the sun, covering them and using a high factor sunscreen. Please avoid swimming for two weeks.

As well as the three laser appointments, you will be asked to attend 3 standard scar therapy appointments in an outpatient clinic. This will be at regular intervals of 4 months (before you start laser treatment then regularly after), and each appointment

will take around 30 minutes. During your appointment, you will be seen by members of the scar therapy team and research team to assess your progress. Photographs will be taken of the scar and you will be asked to complete two short questionnaires about how you feel your scar looks and affects you on a day to day basis. A member of the research team will examine your scar. This may involve touching the scar but should not hurt.

Follow-up

You will be seen for a final check at 9 months. If you are in the control group, you will make 3 visits over 9 months. If you are in the two laser groups, you will make three visits for laser treatment and 2 further standard care appointments after where you will see the research team together with the scar therapy team.

What are the possible advantages of taking part?

Research is a vital part of what the NHS does. We want to offer patients the chance to help us understand all available treatments. We always look at ways to improve treatments. By taking part, we will learn whether combined laser treatment improves scars for patients like yourself. This study may benefit future burns patients.

What are the risks of taking part in this study?

Laser treatment makes your skin feel warm and leads to bruising and tiny holes in your scar; this is what we expect to see with the treatment. The scar being treated will be cooled with a cold pack for your comfort during treatment. Other side effects may include redness, some discomfort or swelling. 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.

Laser treatment may be less effective for patients with darker skin types. There is also an increased risk of permanent changes to skin colour (becoming darker or lighter). If you have a suntan or fake tan at the time of your laser treatment, you may be asked to return in a few weeks once this has faded.

Any treatment, including “standard care” or laser, may not improve your scarring. If you have any problems or queries between visits, then you can contact us using the information below. After the study finishes, if your consultant feels that your scar may still benefit from laser treatment, this will be discussed.

Sometimes, the questionnaires used in studies such as these may bring back some feelings that remind you of the time when you had your burn injury. If you have worries or concerns about your scar or anything else, or if you tell us that you are struggling with your mood, we will suggest a referral to our clinical psychology team. You may have already met them during your previous burn care. Please let us know if you wish to speak to a member of their team or alternatively, you can contact them directly with the details below:

Dr. Emma Hodgkinson, Clinical Psychology, Royal Victoria Infirmary
Telephone: 0191 282 4081

Will I get paid for taking part in this study?

You will not receive any payment for taking part and you will not be refunded for any travel expenses. If you are in the laser treatment group, you will be invited to attend appointments for this treatment. You will not be expected to pay for any of the treatments.

How will you use information about me?

All information about you will be handled in confidence. We will need to use information from your medical records for this research project. This information will include your name and contact details. 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 a 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 my 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. 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.

Where can I find out more about how my information is used?

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to Trust.R&D@nuth.nhs.uk, or
- by ringing us on 0191 2448949.

Who has reviewed this research study?

All research in the NHS has been reviewed by experts and looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been approved by the Bradford Leeds Research Ethics Committee and the Health Research Authority (HRA).

What if relevant new information becomes available?

If there is new information about the treatment being studied, we will tell you about it as soon as possible. We will give you the opportunity to discuss it with one of the research team. If this new information means that we should stop or change the study, we will do this and make sure that you are offered the best treatment.

What if there is a problem?

If you have concerns about any aspect of this study, you should ask to speak to a member of the research team. We will do their best to answer your questions. If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454

Email: nuth.patient.relations@nhs.net

Address: Patient Relations Department

The Newcastle upon Tyne Hospitals NHS Foundation Trust

The Freeman Hospital

Newcastle upon Tyne

NE7 7DN

What will happen to the results of the research study?

The results will be published in medical journals or presented at medical conferences. All the information or data that we publish or present will continue to be anonymous. If you wish to be informed of the results of the study, please inform the research team using the consent form provided.

Who is organising and funding the research?

The study is being coordinated by the Newcastle Hospitals NHS Trust and is funded by the Royal College of Surgeons of England and the Blond McIndoe Research Foundation.

How can I take part in this study or find more information?

If you wish to take part in this study or have any further questions, please speak to a member of the research team or contact them via Karen Smith 0191 2448949. Alternatively, the research team can be contacted through the study email address CLIPSOstudy@gmail.com.