LITEFORM

To be printed on local headed paper

MAIN STUDY PATIENT INFORMATION SHEET
Version 1.2

Lite **T**herapy **E**ffectiveness **F**or **OR**al **M**ucositis Trial

The **LiTEFORM** Study

Invitation

We are inviting you to take part in a research study. Please read the following information to help you decide if you want to take part. It will explain why we are doing this research and what it might mean for you. You don't have to decide straight away and you can talk to your friends/family about it. Ask us if you have any questions or you want to know more.

Key Points

- Most patients who get radiotherapy for head and neck cancer will suffer from pain and sores in the mouth. This is called oral mucositis.
- There is a **new laser therapy** which shines a weak laser light in the mouth. Early studies have shown that it may help healing.
- LiTEFORM is looking to find out how well this laser therapy works and if it should be used widely in the NHS.
- All patients who take part in LiTEFORM will be given their usual treatment and **half will also be given the laser therapy.**
- The results will tell us how good the laser light is at cutting down pain and mouth sores during head and neck cancer treatment. LiTEFORM will also measure any impact on the quality of life for patients.

Please read the following information to see if you may be interested in taking part.

Why is LiTEFORM needed?

- Most patients will get oral mucositis as a side effect of their radiotherapy. These patients are likely to find this affects their ability to talk, eat, drink and find it difficult to swallow. They can get painful sores and ulcers in their mouth, and on their tongue and lips.

- Patients are given help to keep their mouth and teeth clean, have a healthy balanced diet and drink enough water. Patients may also be given painkillers and special mouthwashes and coating gels. We call this the **standard treatment**

- There is a new treatment called **Low Level Laser Therapy**. This involves shining a weak laser light on the lining of the mouth. The aim is to take down swelling, relieve pain and help healing. LiTEFORM will tell us if the laser therapy should be widely used in hospitals to help patients with head and neck cancer in the future.

Why have I been invited to take part in LiTEFORM?

You have been diagnosed with head and neck cancer and are due to have treatment with radiotherapy.

Do I have to take part?

No, it is up to you to decide if you want to take part in LiTEFORM. If you do not want to take part, you will still get the standard treatment that has been arranged by your doctor. If you agree to take part, you can change your mind and withdraw from the study at any time without having to give a reason.

What does taking part involve?

How will the study be carried out?

All LiTEFORM patients will get the standard treatment as if they were not in the study. The difference is that half of the patients will also get the laser light therapy. To make the study fair, both the patients in the study and the research team will not know who is having the laser light therapy.

So, if you decide to take part you will be put in one of two LiTEFORM groups.

Group 1: Standard treatment and **active laser therapy**

If you are put in group 1, you will be given the standard treatment for oral mucositis at your hospital. You will also get laser therapy. Only patients in group 1 will get active laser therapy.

Group 2: Standard treatment and **inactive laser therapy**

If you are put in group 2, you will get the standard treatment for oral mucositis at your hospital. You will also get a 'sham' or inactive laser therapy. This means that the machine will not actually shine any laser light in your mouth during each session.

- **To make sure it is a fair comparison, you won't know which group you are in, nor will your doctor or any of the LiTEFORM team.**

- **You will have an equal chance of being in group 1 as in group 2 (a 50:50 chance).** Your group will be picked by a computer. We call this 'randomisation'. Your doctor will not have any say on which group you are put in.

What will happen first?
A member of the LiTEFORM team will greet you when you come to hospital for your radiotherapy planning clinic. They will ask your permission to voice record their conversation with you and anyone you have brought to support you. This is to help us learn more about the sort of questions people ask about the study.

They will answer any questions you might have. If you are happy to take part, they will ask you to sign a consent form.

What will I have to do?
The LiTEFORM team will see you when you come to hospital for your planned radiotherapy visits and follow up visits.

- You will be given up to three laser therapy sessions every week for 6 weeks.
- Before you start treatment, once a week for 6 weeks, and again at 4 months and 14 months after your last laser therapy session, you will be asked to complete some questionnaires. A member of the team will be on hand to help you.
- You will be asked to drink about half a glass of water as quickly as you can, on four occasions (before radiotherapy, on finishing radiotherapy, 4 and 14 months afterwards).

Collecting Data
- On day 1 of your treatment and weekly for 6 weeks, we will use some information that is already collected about you as part of your standard clinical care. This includes changes in your weight, your dental and nutritional health before, during and after your radiotherapy treatment.

- On one occasion a member of the team will take a photograph of the inside of your mouth (no other facial features). This is so another person can independently check how your oral mucositis has been scored.

- Every week between weeks 2 and 6 of your laser therapy, a member of the team will ask you about your smoking and drinking habits. This is because we know these can affect the lining of the mouth and oral mucositis.

What will the laser therapy session be like?
You will be asked to attend your radiotherapy session about an hour earlier so that there is enough time to have your laser therapy. You only need to do this for three of your radiotherapy sessions each week:

1. A member of the LiTEFORM team will greet you.
2. They will take you to the LiTEFORM treatment room.
3. You will be asked to open your mouth as though you are at the dentist. A small probe will be put in your mouth but it does not need to touch your skin. It will aim at up to six areas in your mouth, including your lips.
4. The session will take about 20 to 30 minutes.
5. After the session is finished, you will be taken to wait for your radiotherapy.

What does the laser feel like?

- You will hear a beeping noise when the machine is switched on
- You might have a warm feeling in your mouth
- You might feel a little bit sick or dizzy afterwards but this is very rare
- You might feel tingling in your mouth
- You will be asked to wear specially made glasses which will have red lights in them. These are to keep your eyes safe and make sure you cannot see if you are getting the active or sham laser therapy. You must wear them for the entire time the laser therapy machine is switched on.
- The person giving you the therapy will be also wearing glasses.

Patient Telephone Interviews

We wish to find out about your views and experiences of LiTEFORM, even if you decide not to take part in the main study. We might not be able to contact everyone, but if we do - a member of the Newcastle University research team will contact you to answer your questions and arrange a date and time to do the interview.

- The telephone interview will take between 20 and 40 minutes.
- If you decide not to take part in LiTEFORM, we may contact you once – about 1 to 2 weeks after we spoke to you about LiTEFORM.
- If you consent to LiTEFORM, we may contact you twice – once at the start (to understand your views about taking part) and again after 4 months or 14 months after your last radiotherapy (to understand your experience of the therapy).

This is separate from the main study, and so you do **not** have to agree to be interviewed. If you are interested, please tell a member of the LiTEFORM team and they will give you more information to take away and read. We will need your written consent for a member of the study team to call you.

Expenses and Payments

You will not receive payment for taking part in LiTEFORM. All parts of the main study will happen when you are already coming to hospital for your standard radiotherapy or follow up appointments.

What happens when the research study stops?

At the end of the study you will continue to receive usual clinical care as decided by your hospital and doctor. You will get the laser therapy as part of the LiTEFORM study for six weeks. We hope that the results of LiTEFORM will help us say if it should be widely used in the future.

What are the benefits of taking part?

Early studies have shown that the laser therapy may help take down swelling and help healing. You will be helping us gather information to learn about using laser therapy as a treatment for patients who are suffering from oral mucositis. We hope that we can improve the quality of life of patients in the future from LiTEFORM. If you want to find out more about taking part in research studies can you visit the NHS Choices Website www.nhs.uk. Here you will also find contact details for your local Patient Advice Liaison Service (PALS) office if you would like to speak to someone.

What are the possible side effects?

The laser machine has been approved for LiTEFORM in your hospital. All of the staff using the machine have been fully trained. The risk of damaging your eye is very small,

but wearing glasses stops the light being accidentally shone in your eyes. If for any reason this did happen, you would be seen by an eye doctor within 24 hours.
At the moment we do not know if there is a risk of shining the laser directly onto tumours, but no studies so far have shown patients becoming any worse from having laser therapy for oral mucositis. For this study we will not be shining the laser any tumours, including the part of the mouth where a tumour is.

If you become pregnant during your 6 week treatment, or think you may be pregnant, it is important that you tell your doctor straight away and we will stop your laser therapy. We hope you might still have time to complete some of the follow up questions as described above.

Further supporting information:

What will happen if I don't want to carry on in the study?
You can withdraw your consent at any time and for any reason, without having to tell us your reason. You will be fully cared for and supported as per your hospital's standard practice.

We will ask if you are happy for us to:

- use any information already collected about you
- continue using information collected as part of your usual care until the end of the study.

What if there is a problem?
If you are not happy with any part of LiTEFORM, you should ask to speak to the study team first who will do their best to help you. **Their contact details are on page 6.** If you are still unhappy you may wish to raise your concerns with someone who is not directly involved in your care. You can contact the Patient Advice Liaison Service (PALS) who provide a confidential service on <site to localise with phone number and email address>

In the unlikely event that you are harmed during the research and this is due to someone's negligence (they were careless) you may have grounds for legal action for compensation, but you may need to meet your own legal costs. NHS indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

Will my GP be told about our involvement in LiTEFORM?
Yes, with your permission we will inform your GP that you are taking part in LiTEFORM. We will send you a copy of this letter so that you can see exactly what has been said. It will also be noted in your hospital medical records so that staff in the hospital know you took part in the study.

What will happen to the results of the study?

- The study is due to finish at the end of 2020.
- The results will be written in medical journals and presented in meetings to other doctors, nurses and researchers.
- The anonymised data might be shared with other researchers and to help with future studies. Your identity will always be protected.
- A report will be written by the study funder and put on their website.
- The results will be available at the end of the study on our website www.liteform.org.uk.

Will the information about me be kept confidential?
Yes. All of the information collected will be entered on computers that are kept secure and password protected.

- We will use a number to identify you instead of using your name.
- Recordings of your voice will be kept secure and any transcripts (written out version) will not include your name or anything that could identify you.
- We will keep a note of your contact details for any telephone interviews you agree to take part in. They will be password protected and only used for this reason.
- Your contact details will never be shared with anyone else.
- You will not be named in any results, reports or anything on our website.

The study information about you and your medical notes will be looked at by people directly involved in the study, as well as by people who are checking the study is running as it should. This may include the Newcastle Clinical Trials Unit at Newcastle University as they are managing the study. It may also include regulatory authorities, sponsor and funder.

Who is organising and funding LiTEFORM?
The main study doctor (also called the 'Chief Investigator') is Mr Michael Nugent, a Surgeon at City Hospitals Sunderland NHS Foundation Trust. The study team also includes senior doctors and nurses, university experts in research studies, and members of the public.

It is managed by the Newcastle University Clinical Trials Unit on behalf of the study sponsor - The Newcastle upon Tyne Hospitals NHS Foundation Trust. It is funded by the National Institute for Health Research, Health Technology Assessment Programme.

Up to 10 hospitals will be taking part in the LiTEFORM study. Each hospital has a study doctor, called an 'Investigator'. The Investigator in your hospital is …… A full list of centres and Investigators is available on our website.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. LiTEFORM has been reviewed and given a favourable opinion by the West Midlands - Solihull Research Ethics Committee.

Patients have been involved in deciding how to do LiTEFORM from the start. For example, patients were supportive of having an inactive laser therapy so that we can get the best results we can from LiTEFORM. We also asked a group of patients who have had head and neck cancer to look at the study information sheets to make sure they are presented in a clear way and easy to understand.

What if I have any questions?
Please ask the doctor or nurse who is looking after you. They can put you in touch with the research team or the Investigator for LiTEFORM at your hospital.

What happens next?
You can take time to think about the study and whether you want to take part. A member of the research team will speak to you when you come back in for your radiotherapy planning clinic. They will go through this information sheet with you and answer any questions before you make your final decision.

Thank you for taking the time to read this information sheet.

Please see team contact details and study diagram on the next page

You can find more information and the progress of the study on our website:
www.liteform.org.uk

LITEFORM team contact details for your hospital:

Principal Investigator:	**Research Nurse:**
Address:	**Address:**
Tel:	**Tel:**

This diagram shows you what happens during LiTEFORM and how long it will take: