

# LiTEFORM light therapy effectiveness for oral mucositis

<b>Submission date</b> 27/03/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/03/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-whether-laser-therapy-helps-reduce-the-pain-and-impact-of-mouth-sores-in-people>

## Contact information

### Type(s)

Public

### Contact name

Mrs Jenn Bingham

### Contact details

Newcastle Clinical Trials Unit  
Newcastle University  
1-4 Claremont Terrace  
Newcastle upon Tyne  
United Kingdom  
NE2 4AE  
+44 191 208 2520  
jenn.bingham@newcastle.ac.uk

## Additional identifiers

### Protocol serial number

33975

## Study information

### Scientific Title

A randomised controlled trial of the clinical and cost effectiveness of low level laser in the management of oral mucositis in head and neck cancer irradiation

## **Acronym**

LiTEFORM

## **Study objectives**

The aim of this study is to establish the benefit of Low Level Laser Therapy delivered 3 times weekly delivered by trained staff in the management of oral mucositis in head and neck cancer irradiation.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

West Midlands - Solihull Research Ethics Committee, 23/03/2017, ref: 17/WM/0096

## **Study design**

Randomized; Interventional; Design type: Treatment, Prevention, Device

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Head and neck cancer

## **Interventions**

Patients will be randomised to one of two groups using a method of random permuted blocks of concealed variable block size and stratified by planned treatment (radiotherapy alone or chemo-radiotherapy), and unilateral or bilateral radiotherapy fields. To ensure concealment of allocation, patients will be centrally randomised by the Newcastle Clinical Trials Unit using a secure web-based system.

Intervention group: Participants receive LLLT plus standard care 3 times weekly by a non-contact method for a period of 6 weeks (from day 1 of radiotherapy dose).

Control group: Participants receive sham LLLT plus standard care 3 times weekly by a non-contact method for a period of 6 weeks (from day 1 of radiotherapy dose).

The LLLT will be a red laser, wavelength 660nm, power output 75mW beam area 1.5cm<sup>2</sup>, irradiance 50mW/cm<sup>2</sup>, exposure time 60 seconds, fluence 3J/cm<sup>2</sup> per spot. LLLT will be administered within 60 minutes before the radiotherapy session, with a minimum of 24 hours between each of the 3 laser therapy sessions. Each session will last 20-30 minutes, with LLLT at 6 pre-determined anatomical sites in the oral cavity.

All patients will also receive the standard care offered for oral mucositis by each centre. Standard care varies across NHS Trusts but typically consists of oral hygiene instruction, topical analgesics and coating gels.

Follow ups will be done at the week 12, month 4 and month 14 standard care head and neck visits.

## **Intervention Type**

Other

## **Primary outcome(s)**

Clinical effectiveness and cost effectiveness of LLLT plus standard care vs standard care alone is measured by comparing the OMWQ-HN score at 6 weeks following the start of radiotherapy (+/- 2 weeks) in the two randomised arms.

## **Key secondary outcome(s)**

1. Effectiveness of LLLT in preventing severe oral mucositis during radiotherapy for head and neck cancer is measured using OMWQ-HN and WHO mucositis at baseline and weekly during 1 to 6 of LLLT
2. Long term reported health related quality of life as measured by EORTC QLQ C30 (version 3.0), EORTC QLQ C30/H&N 35 (EORTC QOL Module for Head and Neck Cancer) and the EQ-5D-5L at baseline, week 6, month 4 and month 14, and MDADI at baseline, week 6, month 4 and month 14
3. Nutritional Parameters as measured by Performance Status Scale's (PSS-HN) collected weekly at baseline, weeks 1-6, month 4 and month 14. Recording of weekly weight changes from baseline during treatment, the quantity of enteral nutrition consumed, number of days of feeding tube in situ
4. Changes in swallowing function measured by the timed water swallow test collected at baseline, week 6 of LLLT month 4 and month 14
5. Pain outcomes as measured by use of analgesics/ topical treatment and pain domain of EQ-5D-5L and OMWQ-HN at randomisation and weekly to week 6 during treatment
6. Safety, specifically adverse events attributed to LLLT and clinical complications notably number of days as inpatient hospital admissions and interruptions in CRT treatment (recorded weekly 1-6 during treatment)
7. Clinical outcomes specifically patient survival, quality-adjusted survival recurrence and persistence of disease at 14 months

## **Economic outcomes:**

1. Incremental cost per change in OMWQ-HN score recorded between baseline and at week 6 of therapy and incremental cost per QALY over 14 months
2. Quality-adjusted life years based upon EQ-5D-5L and EORTC-8D utility scores measured at baseline, week 6 and 4 and 14 months
3. Costs associated with treatment (weeks 0-6) will be collected weekly via the eCRFs (e.g. adverse events and use of analgesics)
4. Health care utilisation based on responses to Health Utilisation Questionnaire administered at 4 and 14 months (assessing: visits to the GP/walk-in clinic/A&E etc.)
5. Participant and family costs collected via the Time and Travel Questionnaire administered at 14 months
6. Total costs of LLLT and sham LLLT measured at 4 and 14 months, from the perspective of the NHS and personal and social services to participants and families

## **Qualitative outcomes as identified through measurement of:**

1. Observations of site initiation visits and device training conducted prior to the opening of each site
2. Interviews with health professionals delivering LLLT conducted and other relevant members

of head and neck cancer team throughout the trial using purposeful sampling, with no more than 2 interviews per staff member

3. Interviews with patients, at 1-2 weeks after the recruitment discussion, and at approximately month 4 or month 14. There will be no more than 2 interviews per patient

### **Completion date**

31/12/2019

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged  $\geq 18$  years diagnosed with HNC
2. Capacity to provide informed written consent
3. Histological diagnosis of squamous cell carcinoma of the oral cavity, oropharynx, nasopharynx, larynx, hypopharynx or unknown squamous cell primary of head and neck origin histologically confirmed
4. (C)RT patients discussed in a Head and Neck MDT meeting and deemed medically fit for an agreed treatment plan for primary or adjuvant radiotherapy  $\pm$  concurrent or induction chemotherapy (cisplatin or cetuximab)
5. Patients planned to receive a minimum of 60Gy to a defined clinical target volume in the oral cavity or oropharynx, or neck levels Ia/b as defined by the current RTOG criteria

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

380

### **Key exclusion criteria**

1. Known to be pregnant or planning to become pregnant within the trial treatment period
2. Parotid tumours
3. Previous radiotherapy for HNC
4. Current/ongoing OM and trismus limiting laser access for treatment
5. Patients who are experiencing active heavy tumour bleeding from the mouth (haemorrhage)
6. Patients for whom the MDT recommend short course palliative radiotherapy
7. Patients on immune suppressant drugs (except low dose steroids)
8. Participation in other trials assessing different treatments for OM
9. Unable to provide written informed consent

**Date of first enrolment**

28/04/2017

**Date of final enrolment**

30/04/2019

**Locations****Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre****Velindre Cancer Centre**

Velindre Road  
Whitchurch  
Cardiff  
United Kingdom  
CF14 2TL

**Study participating centre****Leeds General Infirmary**

Great George Street  
Leeds  
United Kingdom  
LS1 3EX

**Study participating centre****Southampton General Hospital**

Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre****Sunderland Royal Hospital**

Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Freeman Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

## Sponsor information

**Organisation**  
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

**ROR**  
<https://ror.org/05p40t847>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**Alternative Name(s)**  
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will 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?
<a href="#">Results article</a>		01/12/2022	12/12/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			21/03/2024	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes