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LiTEFORM light therapy effectiveness for oral mucositis

Submission date 27/03/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/03/2017	**Overall study status** Completed	
Last Edited 21/03/2024	**Condition category** Cancer	

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

Study website
http://www.liteform.org.uk/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 1.5cm2, irradiance 50mW/cm2, exposure time 60 seconds, fluence 3J/cm2 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 measure
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.

Secondary outcome measures
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

Overall study start date
01/11/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Adults aged ≥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 ± 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 380; UK Sample Size: 380

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
England

United Kingdom

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

Sponsor details
Freeman Hospital
Freeman Road
High Heaton
Newcastle Upon Tyne
England
United Kingdom
NE7 7DN
+44 191 2825789
Aaron.Jackson@nuth.nhs.uk

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The findings from this trial will be disseminated to the relevant stakeholders, including medical professionals involved in the Clinical Commissioning Groups, specialised service providers, cancer research institutes, Clinical Review Groups and patient organisations. Findings will also be published in peer reviewed journals, including open access publications, as well as conferences. The domain name www.liteform.org.uk will be used to retain stakeholder engagement as well as publicising the results. Findings from the qualitative sub study will be fed into the trial, as well as published in selected qualitative papers at the end of the trial.

Intention to publish date
31/12/2020

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?
Results article		01/12/2022	12/12/2022	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			21/03/2024	No	Yes