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LiTEFORM light therapy effectiveness for oral mucositis

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

Contact information

Type(s)
Public

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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

Primary study design
Interventional

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

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 1.5cm2, 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(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 ≥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

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?
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes