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Study on a novel medical device for the treatment of reduced salivation (dry mouth) resulting from radiation therapy

Submission date 28/10/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/10/2011	**Overall study status** Completed	
Last Edited 13/01/2025	**Condition category** Digestive System	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-treating-dry-mouth-after-radiotherapy-head-and-neck-cancer-the-leonidas-2-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10229

Study information

Scientific Title
Long-term Evaluation of the effectiveness Of a Novel Intra-oral electro-stimulator for the treatment of raDiotherapy-ASsociated dry mouth (The LEONIDAS-2 study): a randomised controlled trial

Acronym
LEONIDAS2

Study objectives
The main research question of this study is:

1. Will a new intra-oral removable device provide long-term relief of distressing symptoms of reduced salivation (dry mouth or xerostomia) resulting from radiotherapy to the Head and Neck?

Other research questions are:
1. Will the intra-oral removable device improve salivary gland function (increase of salivary flow) of patients who have hyposalivation resulting from radiotherapy (RT) to the Head and Neck?
2. Will the intra-oral removable device improve quality of life of patients who have dry mouth resulting from radiotherapy (RT) to the Head and Neck?
3. How frequently patients will use the new intra-oral removable device to lessen dry mouth symptoms resulting from radiotherapy (RT) to the Head and Neck?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Yorkshire & Humber Research Ethics Committee - Sheffield, ref: 11/YH/0072

Study design
Randomised; Interventional; Design type: Treatment

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Oral and Gastrointestinal; Subtopic: Head and Neck Cancer, Oral and Gastrointestinal (all Subtopics); Disease: Head and Neck, Oral & Dental

Interventions
Assuming that 20% of the patients of the control group report the successful outcome (30%+ reduction in symptoms on the VAS) and 60% of patients on the active device will do so, the sample size required to detect such a difference in reduction of xerostomia symptoms with 90% power using a cutoff for statistical significance of $p<0.05$ is 70. Considering a potential drop out of 20%, the total number of patients to be enrolled is 84 (42 in the study group and 42 in the control group).

Salivary electrostimulation, Participants will be provided with a electrosimulating device to be applied in the mouth and used as symptoms dictate (max 10min/hour). Participants in the control group will receive a non-active device.; Follow Up Length: 12 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type
Device

Phase
Phase II/III

Primary outcome measure
VAS dry mouth score; Timepoint(s): Month 0 and 12 as part of follow-up appointments

Secondary outcome measures
1.Home diary; Timepoint(s): To record fequency of device application and weekly VAS dry mouth score
2. Quality of Life Measures; Timepoint(s): QoL questionnaires. Month 0, 1, 2, 4, 6, 8, 12 as part of follow up appointments
3. Salivary flow measurement; Timepoint(s): During month 0, 1, 2, 4, 6, 8, 12 of the trial as part of follow-up appointments

Overall study start date
01/11/2011

Completion date
01/11/2014

Eligibility

Key inclusion criteria
1. To be at least 18 years old
2. To have received more than 40 Gy of external beam radiotherapy (RT) for cancer in the head and neck region at least 4 months before entry into the study
3. To have grade 1 or 2 of Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer (RTOG/EORTC) Late Radiation Morbidity Scoring Schema
4. To have a degree of minimum degree of dryness of 50mm (=50mm) on a 100mm Visual Analogue Scale (VAS) scale (0=no dryness; 100=maximum dryness)

5. To have demonstrable residual salivary gland function (increase in salivary flow on appropriate stimulation (e.g. chewing paraffin wax)
6. To have at least one parotid gland; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 84; UK Sample Size: 84

Key exclusion criteria
1. To have severe uncontrolled systemic disease (on the basis of the classification of the American Society of Anesthesiology: ASA IV and ASA V)
2. To have known allergy to materials similar to those used in the investigational product
3. To wear other active implants such as cardiac pacemaker or defibrillator, or hearing aids
4. To have an unstimulated whole salivary flow of 0ml/15min (complete absence of unstimulated salivary flow as measured via sialometry for 15 minutes)
5. To use of pilocarpine as systemic therapy
6. To have grade 3 RTOG/EROTC or no resting saliva (sialometry = 0mL/1.5 min)
7. To have no parotid glands

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eastman Dental Institute
London
United Kingdom
WC1X 8LD

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
The Hatter Institute for Cardiovascular Studies
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Sponsor type
Hospital/treatment centre

Website
http://www.ucl.ac.uk/jro/index

ROR
https://ror.org/042fqyp44

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration