ISRCTN44528835 https://doi.org/10.1186/ISRCTN44528835

A study of patients with dry mouth and sticky saliva during radiotherapy

Submission date
13/08/2014

Recruitment status
No longer recruiting

Registration date
02/09/2014

Overall study status
Completed

Last Edited
11/12/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Xerostomia is a condition where people are not able to produce enough saliva. It results in thicker, more sticky saliva causing a dry mouth along with difficulties in eating, sleeping, speaking and swallowing. As saliva has antimicrobial properties, xerostomia can also lead to poor oral health, with an increase in tooth decay and erosion of tooth enamel. Radiation-induced damage to the saliva glands is one way in which this condition may occur. Radiation-induced xerostomia (RIX) is a common complaint in head and neck cancer (HNC) patients being treated with radiotherapy. Visco-ease is a new product developed for the treatment of RIX. In previous research, Visco-ease has been shown to change the thick, sticky saliva experienced after radiotherapy back to less sticky, thinner saliva. Here, we will be testing a Visco-ease spray that is given under the tongue. HNC patients being treated with radiotherapy will be given the spray and their xerostomia symptoms compared with what they experience when they are given a placebo, or dummy, spray. Each patient that agrees to take part in the research will also be asked to complete a short questionnaire and diary on their xerostomia symptoms and how these symptoms affect their everyday activities. This will help us to see how well the Visco-ease spray works.

Who can participate?
Adult patients over the age of 18 who are being treated at the Beatson West of Scotland Cancer Centre for HNC with radiotherapy.

What does the study involve?
Just before beginning radiotherapy, patients are asked about any previous illnesses and current medications and given a physical examination. They then complete a short questionnaire about whether they feel they have a dry mouth or thick sticky saliva and how these symptoms affect their everyday activities. From their first week of radiotherapy treatment until they finish treatment, they are asked to use the product by applying a spray under their tongue. They are asked to use their spray as often as needed but at least twice a day seven days a week. One group of patients is given a spray containing Visco-ease and one group is given a spray containing a placebo. Neither the patient nor the doctor know which spray is being used at any time. A study nurse helps the patient administer the spray for the first time and they are monitored for one hour afterwards in hospital. During this time patients are asked to complete a

short questionnaire about how their dry mouth feels after taking the spray. Each week, patients return to the clinic and are asked again about medication and any new symptoms, and repeat the questionnaire. Each patient also uses a diary to note how often and when they use the spray. They are also asked to complete the questionnaire about their symptoms at home each evening.

What are the possible benefits and risks of participating?
Visco-ease may help relieve symptoms of dry mouth and sticky saliva, which we expect patients to develop during their radiotherapy treatment. The information we get from this study may allow us, in the longer term, to improve the treatment of HNC patients with RIX. No disadvantages or risks to health have been identified. The components of Visco-ease have all been studied extensively and are natural and common in many foods. Visco-ease simply acts on the surface of the mouth.

Where is the study run from?
This study is sponsored by NHS Greater Glasgow & Clyde and is being performed at The Beatson West of Scotland Cancer Centre, Glasgow.

When is study starting and how long is it expected to run for?
January 2016 to December 2016

Who is funding the study?
Lamellar Biomedical, Ltd (UK)

Who is the main contact?
Dr Claire Paterson, Consultant Clinical Oncologist, Beatson West of Scotland Cancer Centre
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GN14ON413; Eudamed number: CIV-15-11-013988

Study information

Scientific Title
Assessing the safety and effectiveness of Visco-ease for the treatment of Radiotherapy Induced Xerostomia in head and neck cancer patients

Study objectives
Current hypothesis as of 22/01/2016:
Lamellar Biomedical believe that Visco-ease, which is a phospholipid mimetic of naturally occurring extra-alveolar lamellar bodies, could be used to ameliorate xerostomia (dry mouth) following RT, in the head and neck area, by increasing saliva fluidity.

The purpose of this study is to observe and identify changes in disease specific oral Quality of Life (QoL) questionnaire and symptoms taken from the Groningen Radiotherapy-Induced Xerostomia (GRIX) questionnaire and to collect ongoing safety surveillance data on Visco-ease and placebo when administered as an oral spray in subjects with RT induced Xerostomia.

Previous hypothesis:
Lamellar Biomedical believe that Visco-ease, which is a phospholipid mimetic of naturally occurring extra-alveolar lamellar bodies, could be used to ameliorate xerostomia (dry mouth) following RT, in the head and neck area, by increasing saliva fluidity.

The purpose of this clinical follow-up investigator-led study, is to observe and identify changes in disease specific oral Quality of Life (QoL) questionnaire and symptoms taken from the Groningen Radiotherapy-Induced Xerostomia (GRIX) questionnaire and to collect ongoing safety surveillance data of 3 concentrations of Visco-ease and placebo when administered as an oral spray in subjects with RT induced Xerostomia.

Ethics approval required

Old ethics approval format

Ethics approval(s)
West of Scotland REC 4, 05/01/2016, Ref: 15/WS/0281

Study design
Randomised parallel-group double-blind single-centre placebo-controlled trial

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
Radiotherapy Induced Xerostomia (RIX).

Interventions
Current interventions as of 22/01/2016:
1. Visco-ease (19.6 mg/mL LMS-611),1 spray under the tongue twice daily to PRN
2. Placebo (physiological saline), 1 spray under the tongue twice daily to PRN

Previous interventions:
1. Visco-ease (5), 5 mg/ml LMS-611,1 spray under the tongue twice daily to PRN
2. Visco-ease (10), 10 mg/ml LMS-611,1 spray under the tongue twice daily to PRN
3. Visco-ease (20), 20 mg/ml LMS-611,1 spray under the tongue twice daily to PRN
4. Placebo, physiological saline, 1 spray under the tongue twice daily to PRN

Intervention Type
Device

Primary outcome measure
Current primary outcome measures as of 22/01/2016:
The primary outcome is change in GRIX scores from baseline (visit 1) to end of treatment (visit 7). The primary outcome will be compared between Visco-ease and the placebo treatment

Time points for GRIX primary outcome measure:
1. Visit 1 (Baseline): Start of treatment (day 1)
2. Visit 7: End of treatment (day 40 +/- 3 days)

Previous primary outcome measures:
Disease specific oral QoL identified from the Groningen Radiotherapy-Induced Xerostomia (GRIX) questionnaire completed at clinic.

Baseline characteristics will be summarised for all randomised participants. Efficacy endpoints before, after and as the change during each treatment period will be summarised by treatment group.

Time points for GRIX primary outcome measure:
1. Baseline, start of treatment 1 (Day 14)
2. End of treatment 1 (day 18)
3. Start of treatment 2 (day 21)
4. End of treatment 2 (day 25)
5. Start of treatment 3 (day 28)
6. End of treatment 3 (day 32)
7. Start of treatment 4 (day 35)
8. End of treatment 4 (day 39)

Secondary outcome measures

Current secondary outcome measures as of 22/01/2016:
1. Occurrence of any at least possibly device related SAEs throughout the treatment period
2. Number of at least possibly device related SAEs throughout the treatment period
3. Additional safety outcomes including adverse events, withdrawal, vital signs and concomitant medication use
4. Number of treatment administrations as recorded in the patient diary
5. Domiciliary GRIX scores
6. Follow-up GRIX scores taken two weeks after completion of treatment
Secondary outcomes will be compared between Visco-ease and the placebo treatment

Secondary outcome measure time points:
1. SAEs occurring from Visit 1 (start of treatment) until Visit 8 (follow-up contact) will be recorded each week from Visit 2 onwards, and during follow-up where required
2. SAEs will be recorded throughout the treatment period as per (1.)
3. AEs, Vital Signs and Concomitant Medication will be recorded at each visit from start of treatment to final visit (end of study/premature discontinuation visit) and during follow-up where required
4. Daily diary records including number and timing of treatment administrations will be completed at home by the patient each day, from Visit 1 – Visit 7
5. Daily record cards including GRIX questionnaires will be completed at home by the patient each day, from Visit 1 – Visit 7
6. GRIX questionnaire will be completed by the investigator via telephone call with the patient at Visit 8 (14 +/- 5 days after Visit 7)

Previous secondary outcome measures:
Ongoing post market surveillance of Adverse Events (AE)
1. Domiciliary (at home) Symptom scores identified from the GRIX questionnaire
2. Global symptom scores
3. Diary records of use of Visco-ease
4. Adverse Events (AEs)
5. Withdrawal from study
6. Vital signs
7. Use of concomitant medications

Secondary outcome measure time points:
1. Daily record cards including GRIX questionnaires will be completed at home by the patient for the following treatment periods: Treatment period 1 (Day 14-18), Treatment 2 (Day 18-21), Treatment Period 3 (Day 28-32), Treatment Period 4 (Day 35-39)
2. AEs and Concomitant Medication will be recorded at each visit from screening to day 39; final visit (end of study/premature discontinuation visit) and during follow-up where required
3. Vital signs will be recorded at the beginning of each treatment period, (Days 14, 21, 28 & 35) and at the final visit (end of study/premature discontinuation visit) and during follow-up where required

Overall study start date
28/01/2016

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Subject has provided written informed consent
2. Male or female ≥18 years of age
3. Patients prescribed radiotherapy or chemoradiotherapy as primary treatment for head and neck tumours where one or more parotid glands will receive a significant dose of dose of radiation as judged by the CI or PI during the radiotherapy planning process

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 patients screened to randomise 35 patients

Total final enrolment
43

Key exclusion criteria
Current exclusion criteria as of 22/01/2016:
1. Subject is pregnant or breast feeding
2. Subjects with known allergies to egg, soya, or lanolin (sheep's wool grease) based products
3. Subjects with a history of an autoimmune disease with pre-treatment xerostomia (e.g. Sjögrens) or other underlying systemic illness known to cause xerostomia independent of prior

radiation therapy exposure
4. Subjects who have participated in an investigational medicinal product study within 30 days prior to signing consent
5. Any clinically significant disease or condition that may interfere with the study treatment or outcome of the study (at the discretion of the CI or PI)
6. Subjects who are unable to complete the questionnaire or diary
7. Subjects who are judged inappropriate for inclusion in the study by the CI or PI
8. Subjects with head and neck cancer who have had surgery to the primary site. Neck dissection alone is not an exclusion

Previous exclusion criteria:
1. Subject is pregnant or breast feeding
2. Subjects with known allergies to egg and soya based products
3. Subjects with a history of an autoimmune disease with pre-treatment xerostomia (e.g. Sjogrens) or other underlying systemic illness known to cause xerostomia independent of prior radiation therapy exposure
4. Subjects who have participated in an investigational study within 30 days prior to signing consent
5. Any clinically significant disease or condition that may interfere with the study treatment or outcome of the study (e.g., metabolic conditions, renal, cardiac or hepatic conditions)
6. Patients who are unable to complete the questionnaire or diary
7. Patients who are judged inappropriate for inclusion in the study by the CI or PI
8. Patients who have had surgery as primary treatment for head and neck cancer (other than neck dissection alone)

Date of first enrolment
01/02/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Beatson West of Scotland Cancer Centre
Glasgow
United Kingdom
G12 OYN

Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

Sponsor details
c/o Paul Dearie
NHS Greater Glasgow & Clyde
Research and Development
NHS Greater Glasgow and Clyde
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
Scotland
United Kingdom
G3 8SW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
Lamellar Biomedical Ltd (UK)

Results and Publications

Publication and dissemination plan
The findings of this study will be presented at appropriate Head and Neck Oncology conferences and submitted for publication in peer-reviewed radiation oncology journals. The results will also be published on the funder's website: www.lamellarbiomedical.com

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/12/2019	11/12/2019	Yes	No
HRA research summary			28/06/2023	No	No