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Effectiveness of an electro-stimulator for the treatment of dry mouth in patients with Sjogren's syndrome

Submission date
25/07/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
13/12/2019

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Reduced salivation (dry mouth) is a common complaint of individuals with Sjogrens syndrome. It is a distressing condition which can lead to long-lasting oral discomfort, dental infections, diminished quality of life, social isolation and loneliness. As current treatments for dry mouth are often unsatisfactory, expensive and may result in adverse effects, further research in this area is needed. A new electronic device has recently been developed to treat dry mouth. The device, acting as a salivary pacemaker, is applied into the mouth (similar to a boxers mouthguard) for a few minutes, harmlessly stimulates the nerves of the salivary glands (salivary electrostimulation) and does not cause adverse side effects. The aim of this study is to assess the effectiveness of the device in patients with Sjogrens syndrome to demonstrate whether using it daily is an effective treatment for dry mouth. The present study will pave the way for a future large study with a view to provide, for the first time, data regarding the long-term effectiveness of salivary electrostimulation.

Who can participate?
Individuals over 18 years of age who have been diagnosed with primary Sjogren's syndrome.

What does the study involve?
Participants will be randomly allocated to either receive the actual device or a sham device that will not deliver electric stimuli but only tactile stimulation (like using chewing gum). Participants will use the device for 6 months after receiving appropriate instructions, and will be allowed to continue using their routine local therapy for dry mouth (e.g. artificial saliva or sipping water) during the study. Participants will also be asked to attend hospital appointments to measure changes in saliva production and complete questionnaires on their dry mouth sensation. Each participant will keep a home diary of their frequency of use and any changes in dry mouth sensation.

What are the possible benefits and risks for participants?
Apart from helping medical research, study participants will benefit from using a new medication-free treatment that based on previous research - is likely to lessen their dry mouth sensation. No significant risk is expected.

Where is the study run from?
University College London Hospital (lead centre) and Birmingham Dental Hospital.

When is study starting and how long is it expected to run for?
Recruitment started in March 2012 and is expected to close in March 2013.

Who is funding the study?
The study is sponsored by University College London Hospital Trust and funded by Arthritis Research UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11543

Study information

Scientific Title
Long-term effectiveness of a novel intra-oral electro-stimulator for the treatment of dry mouth in patients with Sjogren's syndrome: a feasibility study

Acronym
LEONIDAS-1

Study objectives
A novel electronic device that goes in the mouth (intraoral) has been recently developed to treat dry mouth (xerostomia). The device, acting as a salivary pacemaker, is suggested to harmlessly stimulate nerves of the salivary glands without side effects. The aim of this feasibility study is to test the device on a small group of patients with Sjogren's syndrome (SS) in order to define the most appropriate research design of a future large multi-centre study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Sheffield, 13/01/2012, ref: 11/YH/0423

Study design
Randomised interventional pilot 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
Oral, gastrointestinal and dental

Interventions
Electrostimulation, Intra-oral electrostimulating device (salivary pacemaker)

Intervention Type
Device

Primary outcome measure
Reduction in dry mouth symptoms measured at 1, 2, 4, 5 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2012

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Be at least 18 years of age
2. Have clinical symptoms of xerostomia (dry mouth) due to primary SS syndrome diagnosed on the basis of 2001 EUUSA classification criteria
3. Degree of dry mouth symptoms: a minimum degree of dryness of 50mm (=50mm) on a 100mm VAS scale (0= no dryness; 100 = maximum dryness)
4. NO systemic sialogogue therapy (e.g. pilocarpine) for the duration of the study
5. Female patients of child bearing potential must have a negative pregnancy test within twenty-four hours of enrolment
6. To understand and consent in writing to the procedure
7. To agree to undergo all the examinations and clinical evaluations of the study
8. To have evidence of residual salivary gland function, by demonstrating an increase in salivary flow on appropriate stimulation e.g. citric acid stimulation or chewing paraffin wax)
9. To have unstimulated whole salivary flow higher than 0 ml/15min (unstimulated salivary flow as measured via sialometry for 15 minutes)
10. Male and female particioants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment
30

Key exclusion criteria
1. Severe systemic disease (on the basis of the classification of the American Society of Anesthesiology: ASAIII and ASA IV)
2. 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. Complete lower edentulous status (i.e. possess no lower teeth)
5. To have oral anatomical or disease-related characteristics that preclude the insertion of the

device (e.g. mandibular torus, severe trismus)
6. To be unable or unwilling to cooperate with study procedures
7. To have evidence of no residual salivary gland function (via citric acid stimulation or chewing paraffin wax test)
8. To have an unstimulated whole salivary flow = 0 ml/15min (Absence of unstimulated salivary flow as measured via sialometry for 15 minutes)

Date of first enrolment
01/03/2012

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
The Hatter Institute for Cardiovascular Studies
25 Grafton Way
London
England
United Kingdom
WC1E 6DB

Sponsor type
Hospital/treatment centre

Website
http://www.uclh.org/

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
2015 results in: https://doi.org/10.1111/sji.12291 (added 13/12/2019)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration