

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

<b>Submission date</b> 25/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/12/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Stefano Fedele  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Stefano Fedele

### Contact details

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Oral, gastrointestinal and dental

### **Interventions**

Electrostimulation, Intra-oral electrostimulating device (salivary pacemaker)

### **Intervention Type**

Device

### **Primary outcome(s)**

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

### **Key secondary outcome(s)**

No secondary outcome measures

### **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 participants

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

30

### **Key exclusion criteria**

1. Severe systemic disease (on the basis of the classification of the American Society of Anesthesiology: ASA III 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**

United Kingdom

England

**Study participating centre**

**Eastman Dental Hospital**

London

United Kingdom

WC1X 8LD

## Sponsor information

**Organisation**

University College London Hospitals NHS Foundation Trust (UK)

**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

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary**

Not provided at time of registration