

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of the Low power Diode Laser (980nm) on Xerostomia Treatment

Protocol summary

Study aim

The aim of this study is to examine the effect of diode low power laser (980 nm) on xerostomia

Design

The present study is an interventional before-after clinical trial study with diode laser 980 nm on 28 patients with xerostomia.

Settings and conduct

The patients with xerostomia, who had medical records (diabetes and hypertension) and had referred to the Health Houses of Anzali Health Network, were treated by 980nm diode laser.

Participants/Inclusion and exclusion criteria

People with xerostomia whose unstimulated saliva is less than 0.1 ml in 5 minutes will be included in the study. People with a history of radiotherapy; patients suffering from Sjögren's syndrome or cancers; those who have been under treatment by xerogenic drugs or who don't have willingness to undergo treatment will be excluded.

Intervention groups

Parotid and Sub mandibular glands in patients with xerostomia, (6j, 300mW, 20 seconds) will be exposed to 980 nm diode laser extraorally and their sublingual glands will be intraorally exposed to 980 nm diode laser (4j, 200mW, 20 seconds) every other day for 10 sessions. Saliva of patients will be collected every session 5 minutes before and after laser therapy according to Navazesh technique

Main outcome variables

the volume of saliva; the weight of saliva

General information

Reason for update

Acronym

LLLT

IRCT registration information

IRCT registration number: **IRCT20170911036130N2**

Registration date: **2018-03-23, 1397/01/03**

Registration timing: **retrospective**

Last update: **2018-03-23, 1397/01/03**

Update count: **0**

Registration date

2018-03-23, 1397/01/03

Registrant information

Name

Maryam Basirat

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3348 6411

Email address

basirat@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2017-10-15, 1396/07/23

Expected recruitment end date

2017-12-14, 1396/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the Low power Diode Laser (980nm) on Xerostomia Treatment

Public title

The Effect of the Low Level Laser on Xerostomia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All male and female patients who are referred to Bandar Anzali health network and suffering from xerostomia based on the valid Fox questionnaire and their non-stimulated saliva flow rate is less than 0.1 ml per 5 minutes

Exclusion criteria:

Patients under radiation therapy People with Sjögren's syndrome People with cancer People who take xerogenic drug (antiretroviral, antihistamine, anticholinergic, narcotic anticancer, tricyclic antidepressant, anti-inflammatory, anti-congestion drugs) Patients under other treatments of xerostomia (salivary stimulants, electrical stimulation, acupuncture, and the use of saliva substitutes).

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 28

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

before-after

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Guilan University of Medical Sciences, across Padideh and Khazar Restaurants, Fouman - Saravan Ring Road

City

Rasht

Province

Guilan

Postal code

4194173774

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.GUMS.REC.1395.314

Health conditions studied

1

Description of health condition studied

xerostomia

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Salivary flow rate

Timepoint

5 minutes before and after treatment every other day

Method of measurement

amount (volume and weigh) of saliva

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 980nm Diod laser was applied bilaterally on submandibular glands and parotid glands extra orally (6j , 300mW, for 20 seconds) and it was applied intraorally on sublingual glands (4j , 2000mW, for 20 seconds) every other day for 10 sessions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Lijariki and Aliabad Health Houses; Health Network of Bandar-e Anzali

Full name of responsible person

Nahid Derikvand-Maryam Basirat- Seyyed Ebrahim Seyyed monir

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Anzali Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Nahid Derikvand

Street address

Lorestan University of Medical Sciences, Anooshirvan
Rezaei Square, Khoram Abad, Lorestan, Iran.

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derikvand27124@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Maryam Basirat

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only the information on the main outcome will be published.

When the data will become available and for how long

Six months after the publication of the article.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of data for systematic studies or meta-analysis will be possible.

From where data/document is obtainable

I will provide it to the researchers of academic and scientific institutions via e-mail.

What processes are involved for a request to access data/document

The application should be sent to the researcher or vice chancellor of the Guilan University of medical sciences in an official letter which is approved by the Vice-Chancellor of her /his academic institution.

Comments