

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation the preventive effects of low level laser in head and neck radiotherapy induced xerostomia-a clinical trial

#### Protocol summary

##### Study aim

Determination of the preventive effect of low level laser on radiation-induced xerostomia in patients with head and neck cancer

##### Design

A randomized, Double blinded, controlled clinical trial with purposive sampling with a parallel group design of 34 patients.

##### Settings and conduct

Imam Reza oncology and radiotherapy center and Imam Reza hospital blindness of patients and Outcome assessor about study group

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age range:20-75 Yrs 2. Suffering from head and neck tumors requiring radiotherapy 3. Involving one of major salivary glands in radiation field 4. Total dose exceeding 20 Gry Exclusion criteria 7- 1. Patient or physician dissatisfaction 2. Suffering from minor or major salivary gland tumors 3. Suffering from any systemic disease with potential of xerostomia or consumption of any drug causing xerostomia 4. Presence of xerostomia in initial examination(unstimulated saliva<0.1 ml/min) 5. History of previous radiotherapy 6. Presence of oral mucosal lesions 7. Reoperation of patient during trial

##### Intervention groups

In intervention group we use GaAAs LLL with 810 nm, 200 mw power,3 cm penetration depth using dose 2 j/cm<sup>2</sup> ,on 16 points including: 3 points on each parotid gland,2 points on each sublingual gland,1 point on each sublingual gland and 2 points on each buccal mucosa by continuous wave and contact mode. Laser is used 3 days in week for 4 weeks beginning at the first day of radiotherapy.In control group sham laser is used .

##### Main outcome variables

subjective xerostomia;stimulated and unstimulated saliva

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080906001216N3**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **retrospective**

Last update: **2020-06-14, 1399/03/25**

Update count: **0**

##### Registration date

2020-06-14, 1399/03/25

##### Registrant information

##### Name

Pegah Mosannen Mozaffari

##### Name of organization / entity

research center of Mashhad dental faculty,Mashhad University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 513882950115

##### Email address

mosannenp@mums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

vice chancellor of research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2018-10-23, 1397/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation the preventive effects of low level laser in head and neck radiotherapy induced xerostomia-a clinical trial

**Public title**

The effect of laser on radiation-induced xerostomia in patients with head and neck cancer

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range:20-75 Yrs Suffering from head and neck tumors requiring radiotherapy Involving one of major salivary glands in radiation field Total dose exceeding 20 Gry

**Exclusion criteria:**

Patient or physician dissatisfaction Suffering from minor or major salivary gland tumors Suffering from any systemic disease with potential of xerostomia or consumption of any drug causing xerostomia Presence of xerostomia in initial examination(unstimulated saliva<0.1 ml/min) History of previous radiotherapy Presence of oral mucosal lesions Regration of patient during trial

**Age**From **20 years** old to **75 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**Target sample size: **34****Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, patients do not know whether the laser is on or off. a unique laser system is used in both groups. two groups never meet each other . all protocols are similar.laser safety actions are similar in both groups.in sham laser group a beep sound is played by mobile so that the patint per cive switching the laser beam while le has safety goggles and tha mobile is not in visual field. in laser group the system is really switched on and off.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

research ethics committee of Mashhad university of medical sciences

**Street address**

vice chancellor of research of Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

911735984

**Approval date**

2015-06-20, 1394/03/30

**Ethics committee reference number**

IR.MUMS.REC.1394.251

**Health conditions studied****1****Description of health condition studied**

Radiation-induced xerostomia

**ICD-10 code**

R68.2

**ICD-10 code description**

Dry mouth, unspecified

**Primary outcomes****1****Description**

stimulated and unstimulated saliva

**Timepoint**

before radiotherpay and once weekly during radiotherpay ( mean: 6 weeks) on 8 to 10 a.m.

**Method of measurement**

Unstimulated saliva: during 5 minutes,whole saliva was sputed in glass tube (every 60 minutes , 5 times).saliva was measured in mili liters and grams stimulated saliva: saliva stimulation in 0,30,60,90 and 120 seconds by citric acid 2% soaked swab on lateral borders of tongues

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: GaAlAs Low level laser (LLL ) with 810 nm, 200 mw power,3 cm penetration depth using dose 2 j/cm2 ,on 16 points including: 3 points on each parotid gland,2 points on each sublingual gland,1 point on each sublingual gland and 2 points on each buccal mucosa by continuous wave and contact mode.

**Category**

Prevention

**2**

**Description**

Control group: The laser device is used off

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mashhad Imam Reza Hospital and Reza Radiotherapy-Oncology center

**Full name of responsible person**

Pegah Mosannen Mozafari

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Mashhad Dental School, Azadi Square, Vakilabad Blvd

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mosannenp@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

vice chancellor of reasearch of Mashhad University of medical sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

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Mashhad University of Medical Sciences, Daneshgah St.

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tafaghodiM@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

vice chancellor of reasearch of Mashhad University of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mashhad Dentistry School

**Full name of responsible person**

Mahdokht Rashed Mohasel

**Position**

colleague

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Full name of responsible person**

Zahra Delavarian

**Position**

professor of oral and maxillofacial medicine

**Latest degree**

Specialist  
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## Person responsible for updating data

**Contact**  
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Associate professor of oral and maxillofacial medicine  
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mosannenp@mums.ac.ir  
**Web page address**

## 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Some data including demographic properties, signs and symptoms

### When the data will become available and for how long

One months after article publication.

### To whom data/document is available

Academic researchers

### Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

### From where data/document is obtainable

Dr Pegah Mosannen Mozafari e-mail:  
Mosannenp@mums.ac.ir

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

Sending email to authors. the authors will send data via email during 3 weeks

### Comments