

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial of Assessing of effect of bethanechol on radiation induced xerostomia in patients with head and neck cancers

#### Protocol summary

##### Summary

This study will be done to assay the effect of bethanechol on radiation induced xerostomia in patients with head and neck cancer. The study population includes patients with head and neck cancers who are going under treatment with 5000 centigray radiation with accelerator device in Ramezan Zade Radiotherapy Center. The case and control group each consists of 17 patients. We use random-number table for randomization. The control group is educated for massage therapy of salivary glands and adequate hydration. lemon tablets are administrated for them 3 times a day as placebo. For case group addition to above mentioned protocol, tablets of bethanechol 25 miligram, 3 times a day is administrated. Unstimulated whole saliva is measured at 2, 4 and six weeks after initiation of radiotherapy by spitting method. During the study, the patients and nurse who collects saliva are not aware of kind of the drug used so this study is a double-blind one.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014061813167N3**

Registration date: **2014-10-07, 1393/07/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-10-07, 1393/07/15

##### Registrant information

###### Name

Maryam Nourelahi

###### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1725 5873

##### Email address

m.noorelahi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2014-07-21, 1393/04/30

##### Expected recruitment end date

2014-10-10, 1393/07/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of Assessing of effect of bethanechol on radiation induced xerostomia in patients with head and neck cancers

##### Public title

Effect of bethanechol on xerostomia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with cancers of head and neck region include progressive larynx cancer, progressive hypopharynx cancer and nasopharynx cancer; undergone radiation with 5000 centigray by linear accelerator; using oral protective shield Exclusion criteria: Cardiovascular diseases; gastrointestinal diseases

##### Age

From **20 years** old to **90 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked***No information***Sample size**Target sample size: **34****Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Shahid Sadoughi University of Medical Sciences

**Street address**Shahid Sadoughi University of Medical Sciences,  
Bahonar Squ,Yazd,Iran**City**

Yazd

**Postal code****Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

17/1/48464/پ

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

Cancer of larynx, Hypopharynx, Nasopharynx

**ICD-10 code**

c11.c13.c3

**ICD-10 code description**Malignant neoplasm of larynx, Malignant neoplasm of  
hypopharynx, Malignant of nasopharynx**Primary outcomes****1****Description**

Unstimulated whole saliva

**Timepoint**

2, 4 and 6 weeks after initiation of radiotherapy

**Method of measurement**With milliliter by graduated measuring tube by spitting  
method**Secondary outcomes**

empty

**Intervention groups****1****Description**Massage therapy, adequate hydration. Bethanechol  
tablets 25 miligram are administrated for them 3 times a  
day**Category**

Treatment - Drugs

**2****Description**Massage therapy, adequate hydration. Lemon tablets are  
administrated for them 3 times.**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ramezan Zade Radiotheraoy Center of Yazd

**Full name of responsible person**

Nazila maserat

**Street address**Ramezan Zade Radiotheraoy Center, Motahary Street,  
Yazd,Iran**City**

Yazd

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Nazila maserat

**Street address**

Dentistry University, Dahe Fajr Blvd, Yazd, Iran

**City**

Yazd

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Shahid Sadoughi University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Sadoughi University of Medical Sciences of Yazd  
**Full name of responsible person**  
Mohamadsadegh Alemrajabi  
**Position**  
Resident of oral medicine  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*