

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

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

Protocol summary

Summary

This study will be done to assay the preventive effect of pilocarpin 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. Control group is educated for massage therapy of salivary glands and adequate hydration. lemon tablets are administrated for them 4 times a day which is trickled by normal saline as placebo. For case group addition to above mentioned protocol, 4 drops of pilocarpin eye drop 2%, 4 times a day is administrated instead of normal saline. Un stimulated whole saliva is measured at 2 weeks before the initiation of radiotherapy, on the first day, two and four weeks after initiation of radiotherapy by spitting method. During the study, patients and the nurse who collects saliva are not aware of kind of drug so this study is a double-blind study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042013167N2**

Registration date: **2014-05-13, 1393/02/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-13, 1393/02/23

Registrant information

Name

Maryam Nourelahi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 35 1725 5873

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-05-24, 1393/03/03

Expected recruitment end date

2014-07-25, 1393/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effect of pilocarpin on xerostomia

Purpose

Prevention

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 disease; gastrointestinal disease

Age

No age limit

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

17/1/172724/پ

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

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

Two week before radiotherapy, on the first day, at 2 and
4 weeks after initiation of radiotherapy

Method of measurement

With milliliter by graduated measuring tube by spitting
method

Secondary outcomes

empty

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

Case group is educated for massage therapy of salivary
glands and adequate hydration. lemon tablets are
administrated for them 4 times a day which is trickled by
4 drops of pilocarpin eye drop 2%

Category

Prevention

2**Description**

Control group is educated for massage therapy of
salivary glands, adequate hydration and lemon tablets
are administrated for them for 4 times a day which is
trickled by normal saline as placebo.

Category

Prevention

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

Ramezan Zade Radiotheraoy Center of Yazd

Full name of responsible person**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
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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