Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 35 1725 5873

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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 mililiter 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

Other areas of specialty/work

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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