Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Randomized double blind clinical trial for assessing the effect of Modiff versus placebo on radiation induced xerostomia of head and neck patients.

Protocol summary

Summary

The purpose of this study is to present an effective treatment with long term results to patients with radiation induced xerostomia .Inclusion criteria is the age over 18 years and radiation with at least 40 gray to at least 3 major salivary glands in head and neck and existence of grade 2 xerostomia,it means they need to drink water for each food swallowing .Exclusion criteria is existence of collagen vascular diseases or recurrence of cancer. The study population are the head and neck cancer patients treated in the radiation oncology clinic of Cancer Institute of Imam Khomeini Hospital. The sample size is 30.This study will assess the efficacy of Modiff versus Placebo on the radiation induced xerostomia. It will take 6 mounths from 22 October 2016 to 19 April 2017.The quality of life of patients and their saliva amount will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092629998N1**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Saeedeh Archang

Name of organization / entity

Resident

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 2272

Email address

s-archang@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized double blind clinical trial for assessing the effect of Modiff versus placebo on radiation induced xerostomia of head and neck patients.

Public title

Assessment of Modiff effect on xerostomia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias:xerostomia at least grade 2 based on Avraham Eisbruch trial's grading(grade1:no malfunction, grade 2:need to exess fluid to swallow, grade 3: changes in nutririon ,sleep,speech and other activities); taking more than 40gray radition to head and neck to be more than three major salivary glands in the radition field;age of 18 years and older; at least 3 mounths later than the end of the radation. Exclusion criteria:alcohol and other

drugs consumption that affect salivary glands like anti depressant;history of connective tissue and collagen vascular diseases like sjogren, rheumatoid arthritis, lupus;systemic or local reccurents;need to prenteralnutrition hospitalsation.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

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
Research and Study managment of Tehran University of Medical Sciences

Street address
poorsina avenue, 16azar sreete, Tehran University of Medical Science

City
Tehran

Postal code

Approval date
2016-09-24, 1395/07/03

Ethics committee reference number
IR.TUMS.REC.1395.2836

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
saliva amount

Timepoint
3times in 3 mountes intervals

Method of measurement
collecting saliva in 5 mintusein the 1 scaled test tube

2

Description
quality of life

Timepoint
3times in 3 mountes intervals

Method of measurement
questionare

Secondary outcomes

1

Description
constipation

Timepoint
3times in 3 mountes intervals

Method of measurement
questionare

2

Description
skin dryness

Timepoint
3times in 3 mountes intervals

Method of measurement
questionare

3

Description
quality of sleep

Timepoint
3times in 3 mountes intervals

Method of measurement
questionare

Intervention groups

1

Description
intervention group:Modiff drug.the combination of Althea and Plantago psyllium and mallow.5 gram saschet. every 8 houres each saschet dissolve in 1 glass of water .drinl daily for 3mounths

Category
Treatment - Drugs

2

Description
placebo group:each sachet contains 5 gram wheat flour plus food colouring produced by Magnolia company. every 8 houres each saschet dissolve in 1 glass of water .drinl daily for 3mounths

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Cancer Institute of Imam Khomeyni Hospital

Full name of responsible person
Saeedeh Archang

Street address
Cancer Institute, Imam Khomeini Hospital Complex, Keshavarz boulvar

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Salamat negar Hekmat pazhoohan corporation ofof Medical Science Traditional Medical School of Tehran

Full name of responsible person
Hossein Rezaeizade MD

Street address
Growth Center of Traditional Medical School ofTehran University of Medical Sciences, West Jamali avenue, Vafamanesh street, Heravi square

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Salamat negar Hekmat pazhoohan corporation ofof Medical Science Traditional Medical School of Tehran

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
Cancer Institue of Imam Khomeyni Hospital Complex

Full name of responsible person
Saeedeh Archang

Position
Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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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