

# 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 prenternalnutrition hospitalisation.

**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 hours each saschet dissolve in 1 glass of water .drinl daily for 3months

**Category**

Treatment - Drugs

## 2

### Description

placebo group:each sachet contains 5 gram wheat flour plus food colouring produced by Magnolia company. every 8 hours each sachet 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 boulv

##### 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

#### Street address

Cancer Institue of Imam Khomeyni Hospita Complexl, Keshavarz Boulvar

#### City

Tehran

#### Postal code

#### Phone

+98 21 6119 2585

#### Fax

#### Email

saeedeh.archang@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Cancer Institue of Imam Khomeyni Hospital Complex

#### Full name of responsible person

Ali Kazemian MD

#### Position

Associate Professor

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

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#### Position

Resident

#### Other areas of specialty/work

#### Street address

Cancer Institue of Imam Khomeyni Hospital Complex, Keshavarz Boulvar

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#### Postal code

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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*