

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Efficacy of the *Malva sylvestris* & *Alcea digitata* compound on prevention of radiation induced xerostomia in head and neck cancer patients

#### Protocol summary

##### Summary

The goal of this randomized clinical trial study, is assessment of efficacy of the *Malva sylvestris* & *Alcea digitata* & *Plantago Psyllium* compound on prevention of radiation induced xerostomia in head and neck cancer patients. Inclusion criteria are: head and neck cancer patients who candidate for radiation therapy, with a minimum of 17 and maximum age of 65 years old, having Good Performance status according with ECOG questionnaire criteria, having at least 4 regions of mucositis (based on a measure of mucositis) in the field of radiation therapy. Exclusion criteria: grade 3 & 4 mucositis, candidiasis and oral herpes infection, sudden changes in the patient's condition or disease in which changing the predicted radiation procedure for patient before getting to dose of 50 Gy, failure / need parenteral nutrition (TPN) or hospitalization and unwillingness to continue participation in the study. Patients with a sample size of 44 persons in both two groups, enter the study. Intervention: experimental group received the *Malva sylvestris* & *Alcea digitata* compound and "standard protocol of care", and the control group received placebo and "health care standard protocol". Duration of intervention is started at the beginning of the radiation therapy and continued till 2 weeks after finishing radiation therapy. Xerostomia and quality of life are measured by VAS scale, questionnaire and examination before intervention, 2 and 6 weeks after finishing radiation therapy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015091015860N3**

Registration date: **2015-09-17, 1394/06/26**

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

Last update:

Update count: **0**

##### Registration date

2015-09-17, 1394/06/26

##### Registrant information

###### Name

Ghazaleh Heydarirad

###### Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8877 6027

###### Email address

dr.ghazalrad@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2015-09-16, 1394/06/25

##### Expected recruitment end date

2016-03-15, 1394/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of the *Malva sylvestris* & *Alcea digitata* compound on prevention of radiation induced xerostomia in head and neck cancer patients

##### Public title

Efficacy of the *Malva sylvestris* & *Alcea digitata* & *Plantago Psyllium* on prevention of radiation induced

xerostomia in head and neck cancer patients

## **Purpose**

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria include: 1. head and neck cancer patients who candidate for radiation therapy 2. minimum age of 17 and maximum age of 65 years old 3. having Good Performance status according with ECOG questionnaire criteria 4. having at least 4 regions of mucositis (based on a measure of mucositis) in the field of radiation therapy 5. physically and mentally able to fill out a questionnaire 6. willingness to participate in the study 7. survival more than one year according to the oncologist or treatment team. Exclusion criteria: The use of alcohol, medicines which affecting the salivary glands such as: anti-depression, opioids, anti-hypertensive, antihistamines, diuretics, types of mouthwash and artificial saliva and smoking during the study; Receiving radiation therapy and chemotherapy in the mouth and oropharynx in the six months ago; The history of connective tissue diseases such as Sjogren's syndrome, rheumatoid arthritis, lupus, liver and kidney disease, major depression, diseases involving salivary glands, diabetes, chronic diseases such as diarrhea cause dehydration, immune suppression disorders, myelosuppression, disorders which causing frequent aphthous stomatitis; Sudden changes in the patient's condition or disease in which changing the predicted radiation procedure for patient before getting to dose of 50 Gy; Grade 3 & 4 mucositis; Candidiasis and oral herpes infection; Failure/ need parenteral nutrition (TPN) or hospitalization; Unwillingness to continue participation in the study

## **Age**

From **17 years** old to **65 years** old

## **Gender**

Both

## **Phase**

2

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **44**

## **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**

Tehran University of Medical Sciences

#### **Street address**

Keshavarz boulevard, Tehran University of Medical Sciences, Tehran

#### **City**

Tehran

#### **Postal code**

#### **Approval date**

2015-03-04, 1393/12/13

#### **Ethics committee reference number**

27838

## **Health conditions studied**

## **1**

### **Description of health condition studied**

Radiation induced xerostomia

### **ICD-10 code**

K11.7

### **ICD-10 code description**

Dry mouth, unspecified

## **Primary outcomes**

## **1**

### **Description**

Xerostomia

### **Timepoint**

Before interventin and 2 and 6 weeks after finishing radiation therapy

### **Method of measurement**

VAS scale (determined by Question from patient) & Xerostomia Grade (determined by clinical examination)

## **Secondary outcomes**

## **1**

### **Description**

Quality of life

### **Timepoint**

Before interventin and 2 and 6 weeks after finishing radiation therapy

### **Method of measurement**

EORTC questionnaire

## **Intervention groups**

## **1**

### **Description**

In the experimental group: Malva sylvestris & Alcea digitata & Plantago Psyllium compound and "health care standard protocol", starting at beginning of radiation therapy and will continue up to 2 weeks after finishing radiation therapy, three times a day.

**Category**

Treatment - Drugs

2**Description**

In the control group, placebo and "health care standard protocol", starting at beginning of radiation therapy and will continue up to 2 weeks after finishing radiation therapy, three times a day.

**Category**

Placebo

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

Department of Radiation Oncology, Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ahmad Ameri, M.D, Board of specialists in Radiation - Oncology, Associate Professor

**Street address**

Imam Hossein Hospital, Nezam Abad, Tehran, Iran

**City**

Tehran

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Rezaeizade

**Street address**

Faculty of Traditional Medicine, west. Jamali, Vafamanesh st., Heravi sq., Tehran, Iran

**City**

Tehran

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Ghazaleh Heydarirad

**Position**

Phd of Iranian Traditional Medicine

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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*