

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with Hypozalix (artificial saliva) in the radiation induced xerostomia and quality of life in patients with head- and- neck cancers

#### Protocol summary

##### Summary

The goal of this randomized, single-center, phase II clinical trial study, is comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with Hypozalix (artificial saliva) in the radiation induced xerostomia and quality of life in patients with head and neck cancers. Inclusion criteria are: a minimum of 20 and maximum age of 70 years old; having xerostomia at least grade 1 based on clinical grading CTC; adverse event 4, and at least three months after the end of radiotherapy. Exclusion criteria: sudden changes in systemic conditions like that a patient requires extensive chemotherapy and surgical interventions, Failure / need parenteral nutrition (TPN) or hospitalization and unwillingness to continue participation in the study. Patients with a sample size of 60 persons in both two groups, enter the study. Intervention: Malva sylvestris and Alcea digitata formulation and Hypozalix (both three times daily) are given to patients for 4 weeks. Finally xerostomia and quality of life are measured by VAS scale, questionnaire and examination.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012415860N1**

Registration date: **2014-01-24, 1392/11/04**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-01-24, 1392/11/04

#### Registrant information

##### Name

Ghazaleh Heydarirad

##### Name of organization / entity

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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8877 6027

##### Email address

dr.ghazalrad@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

#### Expected recruitment start date

2014-02-20, 1392/12/01

#### Expected recruitment end date

2015-02-20, 1393/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with Hypozalix (artificial saliva) in the radiation induced xerostomia and quality of life in patients with head- and- neck cancers

#### Public title

Comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with an artificial

saliva in the radiation induced xerostomia and quality of life in patients with head- and- neck cancers

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: xerostomia at least grade 1 based on clinical grading CTC; adverse event 4; age between 20 to 70 years old; physically and mentally able to fill out a questionnaire; willingness to participate in the study and informed consent; at least three months after the end of radiotherapy; not drinking alcohol; drugs affecting the salivary glands like antidepressant, opioids, antihypertensive, antihistamines, diuretics, all kind of mouthwash and artificial saliva; no history of connective tissue disease like Sjogren, rheumatoid arthritis, lupus, liver disease, kidney disease, major depression, diseases involving salivary glands, diabetes, chronic diseases such as diarrhea cause dehydration; the absence of neutropenia, immunosuppression, myelosuppression  
Exclusion criteria: sudden changes in systemic conditions like that a patient requires extensive chemotherapy and surgical interventions; failure/ need parenteral nutrition (TPN) or hospitalization; unwillingness to continue participation in the study.

### **Age**

From **20 years** old to **70 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Office of Research Affairs, Deputy of Research and Technology, Shahid Beheshti University of Medical

##### **Street address**

Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh St., Yemen St.,

Shahid Chamran Highway.

### **City**

Tehran

### **Postal code**

### **Approval date**

2013-12-01, 1392/09/10

### **Ethics committee reference number**

143

## **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 intervention & weeks 2 and 4 after intervention

#### **Method of measurement**

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

### 2

#### **Description**

Quality of life

#### **Timepoint**

Before intervention and 4 weeks after intervention.

#### **Method of measurement**

EORTC questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Other Symptoms

#### **Timepoint**

Before intervention and 4 weeks after intervention.

#### **Method of measurement**

Question from patient

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Hypozalix 100 mL artificial saliva sprays, three times a day, every time two puffs, for 4 weeks.

#### **Category**

Treatment - Drugs

**2**

**Description**

Intervention group 2: Sachets of Malva sylvestris and Alcea digitata formulation, three times a day, each time one sachet into a cup of boiling water, stirred, and after cooling, drink it. For 4 weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

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

**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

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Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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

**Full name of responsible person**

Rasool Choopani M.D, Ph.D, Assistant Professor

**Street address**

No.8 Shams Alley, opposite St tavanir, Vali Asr Street, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

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

**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**

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

**Full name of responsible person**

Ghazaleh Heydarirad M.D

**Position**

Ph.D student of Traditional Medicine

**Other areas of specialty/work**

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**Fax****Email****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*