

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Evaluate the effect of ginger extract on salivary secretion in patients with radiation-induced xerostomia (double-blind study - controlled)

#### Protocol summary

##### Summary

The aim of the present study was to assess the effect of ginger (*Zingiber officinale*) extract on salivation and symptoms and signs of xerostomia in patients undergoing head and neck radiotherapy. Patients who had received a radiotherapy dose of more than 45 Grays in the head and neck region at least 6 months previously, without recurrence of the condition, with xerostomia based on Fox questionnaire, were included in the present study on the condition that the cause of xerostomia was not other medical conditions such as diabetes and Sjögren's syndrome. All the patients gave their informed written consent to be included in the study. Subjects who did not want to participate in the study or did not want to continue for any reason were excluded. A total of 40 subjects were selected from the patients undergoing radiotherapy in the Department of Oncology and Radiotherapy, Golestan Hospital, Ahwaz, Iran, and were asked to fill out the research questionnaire. The salivary flow of the subjects was measured. Forty paper packets were prepared and a code was written on each packet and based on the code, 100 capsules of ginger extract or placebo were placed in each packet. The packets were randomly distributed among the subjects who were asked to take one capsule every 6 hours. After 2 weeks the patients were asked to fill out the questionnaires again. Then their salivary flow was once again measured. A decrease in xerostomia severity and an increase in salivation were the preliminary outcomes of the present research study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013120915723N1**

Registration date: **2014-04-14, 1393/01/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-04-14, 1393/01/25

##### Registrant information

###### Name

Mohammad Shooriabi

###### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1336 7562

###### Email address

sadeghi.d@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology of Ahwaz Jundishapur University of Medical Science under project number mprc-46

##### Expected recruitment start date

2012-03-19, 1390/12/29

##### Expected recruitment end date

2012-11-20, 1391/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluate the effect of ginger extract on salivary secretion in patients with radiation-induced xerostomia (double-blind study - controlled)

##### Public title

Ginger effect on salivary secretion

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria were: 1- Patients had a history of head and neck cancer and its treatment with high-dose radiotherapy of 45 Gy have been.. 2-At least 6 months past the end of radiotherapy patients. 3 - Age above 18 years 4 - confirms xerostomia questionnaire with Fox 5 - to sign a consent form inclusion Criteria excluded : 1 - Pregnancy 2 - Patients with more than 3 months has passed from cancer treatment. 3 - Patients who can not take food by mouth. 4 - Radiation therapy to patients who have not received their full. 5 - Patients with Sjogren's syndrome or other causes of dry mouth (except radiation) are. Exclusion criteria were: 1 - pregnancy during the study 2 - Sensitivity Ginger.

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## 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

Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Blvd.

##### City

Ahvaz

##### Postal code

#### Approval date

2013-04-13, 1392/01/24

#### Ethics committee reference number

ajums.REC.1392.41

## 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

Xerostomia

#### Timepoint

Beginning of the study, two weeks after baseline (end of study)

#### Method of measurement

Questionnaire

### 2

#### Description

Weight of unstimulation saliva

#### Timepoint

Beginning of the study, two weeks after baseline (end of study)

#### Method of measurement

Milligrams

## Secondary outcomes

### 1

#### Description

Improved quality of life

#### Timepoint

Beginning of the study two weeks after baseline (end of study)

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Ginger capsules, 500 mg orally four times daily for two weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Starch capsules, 500 mg orally four times daily for two weeks.

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Docter Shooriabi

**Street address**

Golestan St.

**City**

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Mohammad Shooriabi

**Street address**

Vice Chancellor for Research and Technological  
Development,Ahvaz Jundishapur University of Medical  
Sciences

**City**

ahvaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Mohammad Shooriabi

**Position**

Faculty member

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Mohamad Shooriabi

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Phd

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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*