Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Ahvaz 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research and Technological Development,Ahvaz Jundishapur University of Medical Sciences
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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

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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