Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of Sage (Salvia Officinalis) leaf hydroalcoholic Extract On Radation-Induced Oral Mucositis

Protocol summary

Summary

The objective of this study is to evaluate the effect of Sage officinalis extract on radiation - induced oral mucositis . This randomized double blind clinical trial has been conducted on patients newly diagnosed of head and neck cancers. 40 patients with radiotherapy treatment plan with at least 40 Gray exposure doses to oral cavity according to the treatment protocol and age of 30-60 are selected and divided into two equal numbered groups of case and control. Each group of case and control are divided into two groups of male and female. Exclusion criteria are previous history of radiotherapy, hypersensitivity to mouthwashes, preexisting active oral diseases, any systemic diseases interfering with healing such as diabetes mellitus. From onset of radiotherapy, patients have given either placebo or 2% Sage mouthwashes, three times daily for 7 weeks. Each time patients hold 5 ml of mouthwash in oral cavity for 1 minute and then spit it out. The patients are examined once a week and oral mucositis intensity are measured by Oral Mucositis Assessment Scale (OMAS), which is based on the scores of erythema and ulcer in 9 areas of oral cavity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010410205N2**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2014-02-04, 1392/11/15

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Sage (Salvia Officinalis) leaf hydroalcoholic Extract On Radation-Induced Oral Mucositis

Public title

Evaluation of Salvia Officinalis On Radiation-Induced Oral Mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1) Minimum accumulative dose of 40 Gy according to treatment protocol; 2) Complete exposure of oral cavity to radiation field ; 3) Minimum age of 30, maximum 60 Exclusion criteria : 1)Previous

history of head and neck radiotherapy ; 2)Intolerance or hypersensitivity to the mouthwash; 3) Preexisting active oral disease; 4) Any systemic diseases interfering with wound healing

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
2-3

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
Babol University of Medical Sciences

Street address
Babol, Ganjafrooz avenue

City
Babol

Postal code

Approval date
2013-02-05, 1391/11/17

Ethics committee reference number
2006

Health conditions studied

1

Description of health condition studied
Intensity of radiation induced oropharyngeal mucositis

ICD-10 code
K12.3

ICD-10 code description
Radiation induced mucositis (oropharyngeal)

Primary outcomes

1

Description
Intensity of oral mucositis

Timepoint
Once a week for 7 week

Method of measurement
Oral Mucositis Assessment Scale (OMAS)

Secondary outcomes

1

Description
Hypersesitivity to drug, patient intoerance

Timepoint
Once a week for7 weeks

Method of measurement
History and physical examination

Intervention groups

1

Description
Herbal extract of plant Salvia officinalis are added to a basic gel to make 2% Sage mouthwash. Patients are instructed to use the mouthwash 3 three times daily from onset of radiotherapy for 7 week duration, each time patients hold 5 ml of mouthwash in their oral cavity for 1 minute and then spitted it out.

Category
Prevention

2

Description
A gel which are equalized in taste, odor, shape and color to 2% Sage mouthwash are used as a placebo mouthwash. Patients are instructed to use the mouthwash 3 three times daily from onset of radiotherapy for 7 week duration. Each time patients hold 5 ml of mouthwash in their oral cavity for 1 minute.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Radiotherapy centre of Shahid Rajaie of Babolsar

Full name of responsible person
Dariush moslemi

Street address
Sahid Rajaie hospital, next to Shilat, Shariatie Str

City
Babolsar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research and Technology, Babol University of Medical Sciences
Full name of responsible person
Aliakbar moghadamnia
Street address
Babol University of Medical Sciences, Vice chancellor for research and Technology, ganj afrooz street, babol, mazandaran, iran
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research and Technology, Babol 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