Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The study of selective radioprotective effects of Zataria multiflora against oral mucositis induced by radiotherapy in cancer patients

Protocol summary

Summary

The aim of this study is to assess the effect of Zataria multiflora extract mouthwash on radio-therapy induced oral mucositis. This Randomized double blind clinical trial is conducted on individuals newly diagnosed of head and cancers. 40 patients with radio-therapy treatment plan with at least 50 Gray exposure doses to oral filed according to the treatment protocol are entered in this study and divided into two equal numbered groups of extract and placebo. Exclusion criteria are: allergy to Zataria multiflora, preexisting oral conditions, pregnancy , use of other medications related to oral mucositis during study period, any systemic diseases interfering with healing. From one hour before radio-therapy, patients are given either placebo or 1% Zataria multiflora mouthwashes, three times daily after breakfast, lunch and dinner for 6 weeks. Each time patients hold 5 ml of mouthwash in oral cavity for 2 minute and then spite it out. At the end of each week, oral mucositis intensity is 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: **IRCT201305285830N3**
Registration date: **2013-08-02, 1392/05/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-02, 1392/05/11

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of selective radioprotective effects of Zataria multiflora against oral mucositis induced by radiotherapy in cancer patients

Public title

Effects of Zataria multiflora against oral mucositis induced by radiotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Exclusion criteria are: allergy to Zataria multiflora, preexisting oral conditions, pregnancy , use of other medications related to oral mucositis during study period, any systemic diseases interfering with healing. Inclusion criteria: age older than 18 and less than 60

years; newly diagnosed of head and neck cancers; radio-therapy treatment plan with at least 50 Gray exposure doses to oral filed.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
mazandaran university of medical science

Street address
Mazandaran university of medical science, Joybar 3 way, ImamSq, Sari, Iran

City
sari

Postal code

Approval date
2013-05-29, 1392/03/08

Ethics committee reference number
92-45

Health conditions studied

1

Description of health condition studied
oral mucositis

ICD-10 code
K13.7

ICD-10 code description
Other and unspecified lesions of oral mucosa

Primary outcomes

1

Description
Oral mucositis

Timepoint
Every week for 6 weeks

Method of measurement
Oral Mucositis Assessment Scale- OMAS

Secondary outcomes

1

Description
Pain

Timepoint
Every week for 6 weeks

Method of measurement
Visual analogue pain scale

Intervention groups

1

Description
From one hour before radio-therapy, patients are given 1% Zataria multiflora mouthwashes, three times daily after breakfast, lunch and dinner for 6 weeks. Each time patients hold 5 ml of mouthwash in oral cavity for 2 minute and then spite it out.

Category
Treatment - Drugs

2

Description
From one hour before radio-therapy, patients are given placebo (mouthwashes without Zataria multiflora) , three times daily after breakfast, lunch and dinner for 6 weeks. Each time patients hold 5 ml of mouthwash in oral cavity for 2 minute and then spite it out.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Radiotherapy centre of Shahid Rajaie hospital of Babolsar

Full name of responsible person
Azar Aghamohammadi

Street address
Sahid Rajaie hospital, next to Shilat, Shariatie Str, Babolsar Babol, Iran

City
Babolsar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Reasearch & Technology Deputy of Mazandaran medical science
Full name of responsible person
Ahmad Ali Enayati
Street address
Reasearch & Technology Deputy of Mazandaran medical science , Moalem squer , Sari , iran
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Reasearch & Technology Deputy of Mazandaran medical science
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