

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 spit 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

Azar Aghamohammadi

##### Name of organization / entity

Islamic Azad University, Sari Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1325 3179

##### Email address

azareaghamohamady@iausari.ac.ir

##### 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 spit 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 spit 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

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Azar Aghamohammadi

**Position**

PhD student

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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PhD by research student in traditional medicine

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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*