

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Efficacy of vitamin C in prevention of chemoradiation-induced mucositis in the patients with head and neck cancer

#### Protocol summary

##### Summary

The aim of present study, is to evaluate the effect of vitamin C using in prevention of mucositis induced by chemoradiation. In a single center randomized double blind clinical trial study with placebo control, 60 patients with head and neck cancer who referred to Shahid-Madani educational-medical center of Tabriz University of Medical Sciences will select randomly and with using random numbers table will allocate in two groups of intervention and control group. Inclusion criteria is, age between 15 to 70 years, and Cisplatin treatment regimen with radiotherapy. Exclusion criteria is any oral active infections, oral ulcers, candidiasis, artificial teeh, corticosteroid use, using tobacco, smoking, alcohol, using opioids, and fever more than 38.5 ° C. Patients in intervention group will receive tab 250 mg of vitamin C daily production of Osvah Pharmaceutical Company, and patients in control group will receive daily a placebo which is similar in shape, color, and flavor to the original drug, for a duration of one month. The severity of mucositis as a primary outcome variable will evaluate by using WHO Toxicity Criteria and patients in both group will evaluate weekly for 4 weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015112525239N1**

Registration date: **2015-12-23, 1394/10/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-23, 1394/10/02

##### Registrant information

##### Name

Farshad Seyyed Nejjhad

##### Name of organization / entity

Department Of Radiotherapy

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 4044

##### Email address

seyednejadf@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University Of Medical Sciences.

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-03-20, 1395/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of vitamin C in prevention of chemoradiation-induced mucositis in the patients with head and neck cancer

##### Public title

Efficacy of vitamin C in prevention of mucositis

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: age between 15 to 70 years; Cisplatin regimen with 45-60 Gy radiation. Exclusion criteria: any oral disease like oral active infections; candidiasis; artificial teeh; using tobacco; smoking; alcohol use; using

opioids; and fever more than 38.5 ° C.

### Age

From **15 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

Randomization will done with Using random numbers table.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University Of Medical Sciences

##### Street address

Department of Radiotherapy, Shahid Madani Hospital, Daneshgah Street, Tabriz.

##### City

Tabriz

##### Postal code

#### Approval date

2015-11-24, 1394/09/03

#### Ethics committee reference number

TBZMED.REC.1394.731

## Health conditions studied

### 1

#### Description of health condition studied

Head and neck cancer

#### ICD-10 code

C00-D48

#### ICD-10 code description

Neoplasm of uncertain or unknown behaviour of other and unspecified sites

## Primary outcomes

### 1

#### Description

Severity of mucositis

#### Timepoint

weekly for 4 weeks

#### Method of measurement

WHO Toxicity Criteria

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In Intervention Group: we will give each day a vitamin C tablet 250mg production of Osvah Pharmaceutical Company for a month.

#### Category

Prevention

### 2

#### Description

In Control Group: we will give a placebo of Vitamin C tablet 250 mg production of Osvah Pharmaceutical Company each day for a month.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Madani Hospital

##### Full name of responsible person

Dr Farshad Seyyed Nejjhad

##### Street address

Department of Radiotherapy, Shahid Madani Hospital, Daneshgah Street, Tabriz.

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University Of Medical Sciences.

##### Full name of responsible person

Dr Farshad Seyyed Nejjhad

##### Street address

Deputy of Research and Technology, Central Building

of Number Two, Tabriz University of Medical Sciences,  
Daneshgah Street, Tabriz.

**City**

Tabriz

**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, Tabriz 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**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr. Solmaz Sadeghi

**Position**

Doctor of Medicine (MD)

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

Faculty of Medicine, Tabriz University Of Medical Sciences, Daneshgah Street, Tabriz.

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+98 41 3335 5921

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department Of Radiotherapy, Tabriz University of Medical Sciences.

**Full name of responsible person**

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**Position**

Oncology and radiotherapy Specialist.

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Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr Solmaz Sadeghi

**Position**

Doctor of Medicine (MD)

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

Faculty of Medicine, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

**City**

Tabriz

**Postal code****Phone****Fax****Email****Web page address****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*