

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 Nejjad

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**

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Full name of responsible person

Dr Farshad Seyyed Nejjhad

Position

Oncology and radiotherapy Specialist.

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Full name of responsible person

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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