

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of Selenium on incidence and severity of mucositis in head and neck cancer patients undergoing radio chemotherapy

Protocol summary

Summary

Almost all (90-97%) of patients undergoing head and neck radiation therapy alone or in combination with chemotherapy are being developed mucositis, among which 30% will experience severe mucositis. These complications can lead to treatment interruption or discontinuation of it, at all. So cancer mortality rate will increase. This Study aims to reduce the incidence and severity of mucositis in patients receiving radio chemotherapy by taking selenium supplements. Patients over 18 years with head and neck carcinoma that candidate for radio chemotherapy , normal renal and liver function and no history of using selenium supplements were randomly assigned to either the intervention group (receiving selenium tablets) and control group (Placebo similar to selenium tablets). In this randomized, double-blind, placebo-controlled clinical trial, 84 patients whose meat inclusion criteria were assigned to control and intervention group randomly. Patients in intervention group use selenium 200 milligrams tablets twice daily and control group consumption two placebos per day from the beginning of treatment with radiation by the end of radio chemotherapy sessions. Selenium blood level prior to starting radiotherapy and after treatment completion is measured in all patients. Well as the incidence and severity of mucositis in these patients is measured weekly during drug consumption.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072718612N1**

Registration date: **2016-10-07, 1395/07/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-07, 1395/07/16

Registrant information

Name

Elahe Laali

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 6465

Email address

e_laali@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Selenium on incidence and severity of mucositis in head and neck cancer patients undergoing radio chemotherapy

Public title

Selenium in radiochemotherapy mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria:age over 18 years old;head and neck carcinoma ;radiocemotherapy candidate;liver and kidney normal condition;at least two third of oral cavity is exposed radiotherapy exclusion criteria:under 18 years old;prior history of using selenium;kidney and hepatic failure

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 84

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

Tehran University of Medical Science

Street address

Tehran University of Medical Science, 16 Azar street, Keshavarz blv

City

Tehran

Postal code

Approval date

2014-09-21, 1393/06/30

Ethics committee reference number

93-02-156-26220-123953

Health conditions studied

1

Description of health condition studied

Malignant melanoma of other and unspecified parts of face

ICD-10 code

C43.3

ICD-10 code description

Malignant melanoma of other and unspecified parts of

face

2

Description of health condition studied

Malignant neoplasm of nasal cavity and middle ear

ICD-10 code

C30

ICD-10 code description

Malignant neoplasm of nasal cavity and middle ear

3

Description of health condition studied

Malignant neoplasm of accessory sinuses

ICD-10 code

C31

ICD-10 code description

Malignant neoplasm of accessory sinuses

4

Description of health condition studied

Malignant neoplasm of larynx

ICD-10 code

C32

ICD-10 code description

Malignant neoplasm of larynx

5

Description of health condition studied

Malignant melanoma of lip

ICD-10 code

C43.0

ICD-10 code description

Malignant melanoma of lip

Primary outcomes

1

Description

mucositis

Timepoint

7days after interventionn and then weekly and 7 days after finishing intervention

Method of measurement

Physical examination

2

Description

selenium blood level

Timepoint

prior of radiation start and at the end of radiotherapy sessions

Method of measurement

Spectrophotometry

3

Description

Neutropenia

Timepoint

prior of selenium start and at the end of radiotherapy sessions

Method of measurement

blood level

4

Description

mucositis length

Timepoint

7days after intervencionn and then weekly and 7 days after finishing intervention

Method of measurement

observation

Secondary outcomes

1

Description

npo(non per oral) time

Timepoint

7 days after intervention and then weekly

Method of measurement

Physical examination

2

Description

narcotic use

Timepoint

weekly

Method of measurement

observation

3

Description

weight

Timepoint

prior and at the end of selenium use

Method of measurement

kg

Intervention groups

1

Description

intervention group: Tab selenium 200 mg twice daily during radiotherapy

Category

Treatment - Drugs

2

Description

control group: two placebo tablets per day during radiotherapy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Elahe Laali

Street address

Keshavarz blv

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Center of Rational Drug Use

Full name of responsible person

Dr.M.Hajibabai

Street address

number 2,13 Aban building Karimkhan street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Center of Rational Drug Use

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

Faculty of Pharmacy

Full name of responsible person

Elahe Laali

Position

Pharmacotherapy Resident

Other areas of specialty/work

Street address

Tehran University of Medical Science,16 Azar street, Keshavarz blv

City

Teharn

Postal code

Phone

+98 21 2293 6465

Fax

Email

elahe_laali@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Pharmacy

Full name of responsible person

Zahra Jahangard

Position

Assistant professor

Other areas of specialty/work

Street address

Imam Hospital

City

Tehran

Postal code

Phone

+98 21 6659 3801

Fax

Email

zjahangard@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Elahe Laali

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 21 2293 6465

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