

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of selenium on prevention or alleviation of oral mucositis induced by radiotherapy

Protocol summary

Summary

A randomized, double-blind, placebo-controlled trial conduct to evaluate the effectiveness of selenium 400 mcg/day in prevention and alleviation of the oral radiotherapy induced mucositis. Patients with oral, nasopharynx or hypopharynx cancer will be enrolled in the study. Patients under 18 years old exclude the study. sample size is at least 30 patients.They will be randomly allocated to receive either selenium or placebo. Patients will be graded on the basis of severity of mucositis on the basis of world health organization classification of mucositis on a weekly basis by using WHO scale for 5 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010511192N4**

Registration date: **2015-03-15, 1393/12/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

m_abbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of selenium on prevention or alleviation of oral mucositis induced by radiotherapy

Public title

Effect of selenium on oral inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with diagnosis of oral;nasopharynx or hypopharynx cancer; who recieve at least 5000 centi gray radiation; at lest 2 locations of oral suitable fior radiotherapy Exclusion criteria: Patients under 18 years old

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

Ethics committee, Deputy of Reserch, Shahid Beheshti University of Medical Sciences

Street address

Ethics committee, Deputy of Research, Shahid Beheshti University of Medical Sciences, Arabi street, Velenjak

City

Tehran

Postal code**Approval date**

2014-12-22, 1393/10/01

Ethics committee reference number

54398-2331

Health conditions studied**1****Description of health condition studied**

Mucositis

ICD-10 code

K12

ICD-10 code description

K12.3

Primary outcomes**1****Description**

Mucosistis severity

Timepoint

Bbaseline;first week;second week;Third week;Fourth week; Fifth week

Method of measurement

Clinical examination

Secondary outcomes**1****Description**

Drug hypersensitivity;Headache

Timepoint

Weekly

Method of measurement

Question from patient

Intervention groups**1****Description**

Group selenium: Adminstration of selenium 400 mcg/day orally just before starting radiotherapy and continuing for 5 weeks

Category

Treatment - Drugs

2**Description**

Group placebo: Adminstration of placebo orally just before starting radiotherapy and continuing for 5 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hosein Hospital

Full name of responsible person

Mohammad Abbasinazari

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Naderi

Street address

School of Pharmacy, Nyayesh Junction, Valiasr street

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research, Shahid Beheshti 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

School of pharmacy, Shahid Beheshti University of
Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

Position

PhD in Clinical Pharmacy

Other areas of specialty/work

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Person responsible for updating data

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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