

# 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 receive at least 5000 centigray radiation; at least 2 locations of oral suitable for 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 scientific inquiries

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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*