

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of the effect of selenium supplementation on sonographic findings of salivary glands and inflammatory factors and oxidative stress in patients with thyroid cancer treated with radioactive iodine

#### Protocol summary

##### Study aim

Determining the effect of selenium supplementation on sonographic findings of salivary glands and inflammatory factors and oxidative stress in patients with thyroid cancer treated with radioactive iodine

##### Design

Clinical trial, randomized, double-blind, randomized control group of 60 patients. Randomization is done using a valid website and 4-block method.

##### Settings and conduct

This clinical trial will be performed in the special clinic of Al-Zahra Hospital. Selenium and placebo are prescribed to the patient in exactly the same packaging. Patients and researchers will not be aware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: • Age 20 to 65 years Diagnosis of thyroid cancer by imaging, such as ultrasound, computed tomography, magnetic resonance imaging, and positron tomography (PET) scan

##### Intervention groups

Intervention group: Patients who receive a selenium capsule containing 200 micrograms of selenium per day for 10 days (3 days before treatment with radioactive iodine to 6 days after treatment with radioactive iodine). Control group: Patients receiving a placebo capsule containing 200 micrograms of maltodextrin per day for 10 days (3 days before radioactive iodine treatment up to 6 days after radioactive iodine treatment)

##### Main outcome variables

Before and after studying the clinical status of salivary glands, blood CRP, oxidative stress indices including total antioxidant capacity (TAC) and total oxidative capacity (TOS) and the sense of taste and secretion of salivary glands are evaluated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201129049534N6**

Registration date: **2021-09-16, 1400/06/25**

Registration timing: **prospective**

Last update: **2021-09-16, 1400/06/25**

Update count: **0**

##### Registration date

2021-09-16, 1400/06/25

##### Registrant information

##### Name

Mohammad bagherniya

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 3183

##### Email address

bagherniya@nutr.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-06, 1400/07/14

##### Expected recruitment end date

2022-10-06, 1401/07/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of selenium supplementation on sonographic findings of salivary glands and inflammatory factors and oxidative stress in patients with thyroid cancer treated with radioactive iodine

## Public title

Evaluation of the effect of selenium on patients with thyroid cancer treated with radioactive iodine

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ages 20 to 65 Diagnosis of thyroid cancer by imaging, such as ultrasound, computed tomography, magnetic resonance imaging, and positron tomography (PET) scan

### Exclusion criteria:

History of sialadenitis (inflammation of the salivary glands) Sjogren's history of collagen vascular disease involving the salivary glands. History of any salivary gland surgery Follow a special diet in the last 3 months Pregnancy and lactation Patient dissatisfaction to participate in the study Taking dietary supplements in the last 3 months Suffering from certain diseases such as diseases caused by congenital diseases, immune system defects, etc.

## Age

From **20 years** old to **65 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is done individually. Entry of each patient into the intervention or control group is done randomly with the help of 4 blocking. This is done using a reputable random number generation website. (Random number generation website: <https://www.sealedenvelope.com/simple-randomiser/v1/li-sts>)

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study will be double blinded so that the researcher and the subjects will not know which group they belong to. For blinding, selenium and placebo capsules are prepared in the same shape, color and size. These capsules are coded by someone other than the researchers (A and B) and then the capsules are given to patients. Until the end of the study and after analyzing the data, researchers will not know about the intervention and control groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

##### Street address

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-09-05, 1400/06/14

#### Ethics committee reference number

IR.MUI.MED.REC.1400.420

## Health conditions studied

### 1

#### Description of health condition studied

Thyroid cancer

#### ICD-10 code

D44.0

#### ICD-10 code description

Neoplasm of uncertain behavior of thyroid gland

## Primary outcomes

### 1

#### Description

Clinical status of salivary glands

#### Timepoint

At baseline and end of the study

#### Method of measurement

Ultrasound of major salivary glands (including examination of echogenicity, size, margin and contour)

### 2

#### Description

C reactive Protein (CRP)

#### Timepoint

At baseline and end of the study

#### Method of measurement

ELISA test

### 3

**Description**

Total oxidative stress

**Timepoint**

At baseline and end of the study

**Method of measurement**

Commercial diagnostic kit

### 4

**Description**

Total antioxidant capacity

**Timepoint**

At baseline and end of the study

**Method of measurement**

Commercial diagnostic kit

### 5

**Description**

Sense of taste

**Timepoint**

At baseline and end of the study

**Method of measurement**

Questionnaire designed by the researcher

### 6

**Description**

The rate of salivary gland secretion

**Timepoint**

At baseline and end of the study

**Method of measurement**

Questionnaire designed by the researcher

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Patients receiving a selenium capsule containing 200 micrograms of selenium per day for 10 days (3 days before treatment with radioactive iodine to 6 days after treatment with radioactive iodine)

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Patients receiving a placebo capsule containing 200 micrograms of maltodextrin per day for 10 days (3 days before radioactive iodine treatment to 6 days after radioactive iodine treatment)

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Al-Zahra Hospital

**Full name of responsible person**

Sepide Amini Semiromi

**Street address**

Soffe Blvd

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746 75731

**Phone**

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**Email**

amini.spide@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Hagh Joy Javanmard

**Street address**

Hezar-jerib Ave

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**Postal code**

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**Email**

ethics@behdasht.gov.ir

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

Yes

**Title of funding source**

Esfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Bagherniya

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Bijan Iraj

**Position**

Endocrinology and metabolism

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Endocrinologist

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## Person responsible for updating data

### Contact

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Study information will be published after the individuals are unidentified and after the project is completed.

**When the data will become available and for how long**

Access period starts six months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

For further analysis

**From where data/document is obtainable**

Dr. Mohammad Baghernia bagherniya@nutr.mui.ac.ir

**What processes are involved for a request to access data/document**

After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided

**Comments**