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

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Iran (Islamic Republic of)

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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 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/lists)

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
Isfehan

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
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Sponsors / Funding sources

1

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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
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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