

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluating the protective effect of oral ginseng in patients with thyroid cancer following administration of high levels of radioactive iodine by measuring micronuclei and some biochemical factors

#### Protocol summary

##### Study aim

Evaluation of the role of radioprotective effect of oral Ginseng on patients with thyroid cancer.

##### Design

The clinical trial has four groups (control, placebo, ginseng before treatment and ginseng before and after treatment). Randomize groups using dice. The expected sample size in each group is 20, that is 80 in total.

##### Settings and conduct

The study is double-blind, meaning that the researcher and clinical caregivers are blind to the categorization of the study groups. The study is being carried out in the Nuclear medicine Unit of Shiraz Namazi Hospital. Blood samples were taken from patients before treatment and once after treatment. Patients' blood in the laboratory is evaluated for micronuclei and changes in a number of biochemical factors.

##### Participants/Inclusion and exclusion criteria

People between the ages of 30 and 60 with thyroid cancer who have undergone thyroid surgery and are being treated for the first time can be enrolled. Patients who have undergone radiotherapy or chemotherapy in the past year, are smokers, have a specific illness, or take a particular medication cannot be enrolled.

##### Intervention groups

We have four groups in the study. Intervention group 1: Control group receiving no supplement. Intervention group 2: receive 500 mg of ginseng the day before treatment. Intervention group 3: receive 500 mg of ginseng one day before treatment and one day after treatment. Intervention group 4: receive placebo before treatment. The root of the ginseng plant was powdered in 500 mg capsules from Isfahan Ponic Medic.

##### Main outcome variables

Micronucleus production rate; Total antioxidant capacity; The rate of oxidative stress production

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200115046136N1**

Registration date: **2020-07-21, 1399/04/31**

Registration timing: **retrospective**

Last update: **2020-07-21, 1399/04/31**

Update count: **0**

##### Registration date

2020-07-21, 1399/04/31

##### Registrant information

##### Name

Vida Omrani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3628 0065

##### Email address

v\_omrani@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-29, 1398/11/09

##### Expected recruitment end date

2020-04-28, 1399/02/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluating the protective effect of oral ginseng in patients with thyroid cancer following administration of high levels of radioactive iodine by measuring micronuclei and some biochemical factors

## Public title

Radioprotective effect of ginseng in thyroid cancer patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients between the ages of 30 and 60 who had thyroid cancer and underwent thyroid surgery. Patients who first receive radioactive iodine.

### Exclusion criteria:

People who have undergone radiotherapy or chemotherapy in the last year. People with certain genetic diseases. People taking medications for heart and kidney failure, and those who take Warfarin anticoagulants definitively. People who smoke. People who are radiant People who have taken ginseng in the last month.

## Age

From **30 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Investigator
- Outcome assessor

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The simple method of randomization is with the dice tool. We throw dice for everybody, If number 1 and 2 come in group A, if number 3 and 4 come in group B, and if number 5 and 6, person falls into group C. In addition to the control group, there were two intervention groups and one placebo group. Names are put in sealed envelopes by someone other than the researcher.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patients are named in groups A, B, C, D and the person evaluating the patients does not know what group the patients are in and is kept blind to the study. The patient is also given a complete description of one of the treatment or control or placebo groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Vice Chancellor for Research and Technology, Seventh Floor, Shiraz University of Medical Sciences, Zand Street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

#### Approval date

2019-11-12, 1398/08/21

#### Ethics committee reference number

IR.SUMS.REC.1398.832

## Health conditions studied

### 1

#### Description of health condition studied

thyroid cancer

#### ICD-10 code

C73

#### ICD-10 code description

Malignant neoplasm of thyroid gland

## Primary outcomes

### 1

#### Description

The level of micronuclei in lymphocytes of patients

#### Timepoint

At baseline (before intervention) and 48 hours after treatment

#### Method of measurement

Examination of lymphocytes of patients under the microscope after laboratory procedures.

## Secondary outcomes

### 1

#### Description

Total antioxidant capacity

#### Timepoint

Before treatment and 48 hours after treatment

#### Method of measurement

Using the ELISA 96 kit

## 2

### **Description**

Ischemic modified albumin

### **Timepoint**

Before treatment and 48 hours after treatment

### **Method of measurement**

Using the ELISA method

## 3

### **Description**

The rate of malondialdehyde production in the process of oxidative stress

### **Timepoint**

Before treatment and 48 hours after treatment

### **Method of measurement**

Using the ELISA method

## 4

### **Description**

Evaluation of hepatic Alanine transaminase

### **Timepoint**

Before treatment and 48 hours after treatment

### **Method of measurement**

Using the ELISA method

## 5

### **Description**

Evaluation of hepatic enzyme Aspartate aminotransferase

### **Timepoint**

Before treatment and 48 hours after treatment

### **Method of measurement**

Using the ELISA method

## 6

### **Description**

Blood urea nitrogen test

### **Timepoint**

Before treatment and 48 hours after treatment

### **Method of measurement**

Using the ELISA method

## 7

### **Description**

Evaluation of Creatinine level

### **Timepoint**

Before treatment and 48 hours after treatment

### **Method of measurement**

Using the ELISA method

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: The group received one capsule containing 500 mg of Korean Ginseng (Panax Ginseng)

from Isfahan Ponic Medicines Company, completely herbal with no chemical additives the day before treatment. The ginseng root is a butter that is powdered and poured into the capsule and used orally.

#### **Category**

Prevention

### 2

#### **Description**

Intervention group: Intervention group II: The subjects in this group receive one ginseng capsule one day before treatment and one day after treatment. The consumable material is pure powdered Ginseng root that is poured into the capsule. It is free of any chemical additives and is manufactured by Isfahan Ponic Drug Company.

#### **Category**

Prevention

### 3

#### **Description**

Control group: Control group 1: Take one empty capsule as placebo one day before treatment.

#### **Category**

Placebo

### 4

#### **Description**

Control group: The second control group received no supplementation and received routine treatment.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Namazi hospital

##### **Full name of responsible person**

Dr reza fardid

##### **Street address**

Namazi Hospital, Namazi Square, Shiraz

##### **City**

Shiraz

##### **Province**

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##### **Postal code**

7193711351

##### **Phone**

+98 71 3647 4332

##### **Fax**

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##### **Email**

nemazee\_inf@sums.ac.ir

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.reza fardid

**Street address**

central building of Shiraz University of Medical Sciences, opposite the Palestinian Street, Zand Street

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**Province**

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**Phone**

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info@sums.ac.ir

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Reza fardid

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Radiobiology and Radio safety

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Paramedical School of Shiraz University of Medical Science, Meshkin fam Street

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Ph.D.

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### Person responsible for updating data

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

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**Postal code**

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**Phone**

0098713270238

**Email**

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### Sharing plan

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

Undecided - It is not yet known if there will be a plan to

make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available