Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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.t 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
Fars
Postal code
7193711351
Phone
+98 71 3647 4332
Fax
+98 71 3647 4326
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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7134814336
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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
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Radiobiology and Radio safety
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Person responsible for updating data

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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