

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The radioprotective effect of oral nanocurcumin in thyroid cancer patients after high dose radioactive iodine administration by examining the amount of inflammatory factor TNF $\alpha$ by ELISA test in patients blood serum

#### Protocol summary

##### Study aim

1-Reducing the side effects of radioactive iodine radiation in thyroid cancer patients using nanocurcumin radiation protection

##### Design

Clinical trial with control and intervention group, with parallel groups, single-blind, randomized, phase 3 was conducted on 44 patients.

##### Settings and conduct

In this experiment, 2 groups will be selected, and blood will be taken from all the people twice during the study, once before the treatment and once after the treatment. Given that we have 2 groups, data randomization: people are categorized and placed in groups completely randomly. The study is a single-blind study and the patients are blind to the study.

##### Participants/Inclusion and exclusion criteria

the dose received by the patients should be between 150 and 200 mci and the age of the patients should be between 24 and 79 years. Exclusion criteria: a person has undergone radiotherapy or chemotherapy in the last year, has a certain genetic disease, takes certain drugs, is a smoker, or has been exposed to radiation.

##### Intervention groups

This study is conducted on patients with differentiated thyroid cancer referred to the nuclear medicine department of Namazi Hospital in Shiraz, whose received dose is 150 to 200 mci. The control group receives a placebo.

##### Main outcome variables

A blood sample is taken and evaluated once before the radiopharmaceutical and once a week after the treatment.

#### General information

##### Reason for update

##### Acronym

clinical trail

##### IRCT registration information

IRCT registration number: **IRCT20220212054005N1**

Registration date: **2023-02-18, 1401/11/29**

Registration timing: **retrospective**

Last update: **2023-02-18, 1401/11/29**

Update count: **0**

##### Registration date

2023-02-18, 1401/11/29

##### Registrant information

###### Name

Nazila Keshavarz

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3646 8641

###### Email address

nazilakeshavarz@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-01, 1401/04/10

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

2022-08-21, 1401/05/30

##### Actual recruitment end date

2022-09-21, 1401/06/30

##### Trial completion date

2022-09-21, 1401/06/30

##### Scientific title

The radioprotective effect of oral nanocurcumin in thyroid cancer patients after high dose radioactive iodine administration by examining the amount of inflammatory factor TNF $\alpha$  by ELISA test in patients blood serum

**Public title**

clinical

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patient informed satisfaction dose received by patients should be between 150 to 200 mci patients should be 24 to 79 years old

**Exclusion criteria:****Age**

From **24 years** old to **79 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **44**

More than 1 sample in each individual

Number of samples in each individual: **2**

In order to evaluate the inflammatory factor ,blood samples are taken and evaluated once before the radiopharmaceutical and once a week after the treatment.

Actual sample size reached: **44**

More than 1 sample in each individual

Actual sample size in each individual: **2**

In order to evaluate the inflammatory factor ,blood samples are taken and evaluated once before the radiopharmaceutical and once a week after the treatment.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done in a simple way, so that one of the study groups are considered to be lions and the other group to be lines, and based on the desired sample size, the same number A coin is tossed and people are randomly assigned to two groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The study is one-way blinded and the study participants are blinded to the intervention in such a way that the placebo is prepared from drug-colored capsules containing a little starch and the patients do not know whether they are receiving the drug or the placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics com Emittee of Shiraz University of Medical Sciences

**Street address**

namazi hospital

**City**

Shiraz

**Province**

Fars

**Postal code**

714678813

**Approval date**

2022-06-25, 1401/04/04

**Ethics committee reference number**

IR.SUMS.REC.1401.207

**Health conditions studied****1****Description of health condition studied**

Thyroid cancer

**ICD-10 code**

C75.0

**ICD-10 code description**

Malignant neoplasm of parathyroid gland

**Primary outcomes****1****Description**

TNF factor

**Timepoint**

evaluate the inflammatory factor ,blood samples are taken and evaluated once before the radiopharmaceutical and once a week after the treatment.

**Method of measurement**

Eliza reader

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Considering that our goal is to be able to use the results of the study to improve the harmful effects caused by radiation in the treatment of

patients, therefore, the nanomicelle curcumin sample of Erin Salamat Sina Company approved by the Ministry of Health as a dietary supplement with a dose of 40 mg of nano curcumin that is consumed. These capsules are allowed to be taken one per day. Therefore, in order to conduct this study, one capsule per day will be prescribed according to the standard drug protocol three days before and seven days after the treatment.

#### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Namazi hospital

###### Full name of responsible person

ahmad hoseynzadeh

###### Street address

Namazi SQUARE ,Namazi Hospital

###### City

Shiraz

###### Province

Fars

###### Postal code

7193613311

###### Phone

+98 71 3612 5258

###### 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

Vahid Hoseyni

###### Street address

Zand Street. Central Building of Shiraz University of Medical Sciences

###### City

Shiraz

###### Province

Fars

###### Postal code

7134814336

###### Phone

+98 71 3230 5410

###### Email

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

seyed Mohammad javad mortazavi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Radiobiology and Radio safety

##### Street address

Shiraz, Zand Street, Imam Hossein Square, Shiraz Medical Faculty

##### City

Shiraz

##### Province

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##### Postal code

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+98 71 3230 3544

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mortazavismj@gmail.com

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

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Associate professor

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Nazila Keshavarz

**Position**

Technoloby radiology

**Latest degree**

Bachelor

**Other areas of specialty/work**

Radiology

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**City**

Shiraz

**Province**

Fars

**Postal code**

71913311

**Phone**

+98 71 3646 8641

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

No - There is not 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**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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