

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 α 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 α 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

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7193613311

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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

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7134814336

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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

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

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

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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

seyed Mohammad javad mortazavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Radiobiology and Radio safety

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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

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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