

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the protective effects of nanocurcumin against iodine therapy's side effects in thyroid cancer patients: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Summary

Objective: To study the protective effect of curcumin against the side effects of radioiodine therapy in patients with thyroid cancer Type of study: randomized, double-blind, placebo-controlled clinical trial population groups: patients with newly diagnosed thyroid cancer who are candidate for radiotherapy. Method: patients will randomly divided in three groups, in group one patients will take 80 mg nano curcumin twice a day, starting From one week before until three weeks after radioiodine therapy. Group two takes 40 mg nano curcumin with the same structure, and group three takes placebo as follow. The consequences of the study: the incidence and severity of oral mucositis and dysgenesis, In week one and three after iodine therapy and also reduction of the activity of the salivary glands and the success rates of iodine-131 treatment after one year of treatment. The nausea during the first week after radioiodine therapy, Compared counts of the white blood cells and platelet three weeks, two months and one year after treatment between drugs and placebo groups, The prevalence of patient complaints after iodine therapy, The Plasma levels of curcumin and also ALT and AST variation, two and four weeks after taking the drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030917006N2**

Registration date: **2016-12-09, 1395/09/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Narjess Khatoun Ayati

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences. (Primary sponsor)

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the protective effects of nanocurcumin against iodine therapy's side effects in thyroid cancer patients: a randomized, double-blind, placebo-controlled clinical trial

Public title

The protective effects of nanocurcumin against unpleasant effects of radiotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 65; patients with papillary or follicular thyroid cancer; Desire to join to study
Exclusion criteria: previous history of radioiodine therapy; history of head and neck radiotherapy; previous history of thyroid surgery; pregnancy; lactation; history of chronic rheumatologic disease; history of LASIK or PRK on eye or surgery of salivary glands; PT less than normal

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ahmad Abad Street, Mashhad

City

Mashhad

Postal code

9919991763

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

922435

Health conditions studied

1

Description of health condition studied

Tyroid cancer

ICD-10 code

C73

ICD-10 code description

Malignant neoplasm of thyroid gland

Primary outcomes

1

Description

presence/severity of mucositis

Timepoint

first and third week post drug administration

Method of measurement

observation, physical examination, laboratory assessment

2

Description

changes in taste

Timepoint

one and three weeks post radioiodine therapy

Method of measurement

observation, physical examination

3

Description

Xerestomia

Timepoint

one and three weeks post radioiodine therapy

Method of measurement

observation, physical examination

Secondary outcomes

1

Description

Blood cell count

Timepoint

two and twelve months post radioiodine therapy

Method of measurement

Laboratory test

2

Description

Tumour recurrence (local or distant)

Timepoint

one year post radioiodine therapy

Method of measurement

Physical examination, Lab results, Ultra sonography, Whole body iodine scan

Intervention groups

1

Description

intervention group (1): taking 80 mg nano-curcumin capsules twice daily from one week before to three weeks after radioiodine therapy.

Category

Treatment - Drugs

2**Description**

intervention group (2):taking 40 mg nano-curcumin twice daily,from one week before to three weeks after radioiodine therapy.

Category

Treatment - Drugs

3**Description**

Control group:taking placebo capsules twice daily in group 3(Control group)from one week before to three weeks after radioiodine therapy.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Nuclear Medicine Research Center

Full name of responsible person

Dr. Narjes Ayati

Street address

Mashhad. Ahmadabad street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences. (Primary sponsor)

Full name of responsible person

Dr. Mohsen. Tafaghodi

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Mashhad. Daneshgah street. Ghoreishi building. F2.

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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

Vice chancellor for research, Mashhad University of Medical Sciences. (Primary sponsor)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Ghaem Nuclear Medicine Research Center

Full name of responsible person

Dr. Narjess Ayati

Position

Assiastant Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty