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: pateints 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 curcumine with the same structure, and group three takes placebo as follow. The consequences of the study: the incidence and severity of oral mucositis and dysgenesia,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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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
Pysical 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
Street address
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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