Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial to evaluate the role of radioprotection effect of curcumin in peripheral blood lymphocytes of patients with differentiated thyroid carcinoma treated with Iodine-131, by micronucleus assay

Protocol summary

Summary

Objectives: There are several treatments in patients with thyroid cancer, one of the treatment after total thyroidectomy is radioiodine therapy, which has primary and late complications like genetic effects. In order to reduce the genetic effects Nano-curcumin supplements were used. Design: The study was performed in patients with differentiated thyroid cancer who received the first dose of radioactive iodine after surgery. Intervention: Patients were randomly divided into two groups.(Sample size = 20) Group A patients receiving 150 mCi of iodine 131 with a daily dose of 160 mg of Nano-curcumin 3 days before radioiodine therapy up to 10 days. Group B patients received treatment with 150 mCi of iodine 131 without a daily dose of Nano curcumin. Participants: All patients with thyroid carcinoma that has not received an ablation dose of radioiodine; thyroid cancer confirmed by biopsy; all patients have total thyroidectomy; TSH level before the administration of radioiodine is higher than 30 IU/ML. Method: a blood sample (5 cc) before treatment and 7 days after the administration of iodine taken and transferred to cytogenetic lab to evaluate genetic damages, at the end of study we compared two groups in reducing genetic damage with or without Nano-curcumin.

General information

Acronym

Differentiated Thyroid Carcinoma

IRCT registration information

IRCT registration number: **IRCT2016020526377N1**
Registration date: **2016-04-19, 1395/01/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-19, 1395/01/31

Registrant information

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Maryam Farhadi

Name of organization / entity

Shahid Beheshti University of Medical science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-04-25, 1394/02/05

Expected recruitment end date

2015-12-16, 1394/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the role of radioprotection effect of curcumin in peripheral blood lymphocytes of patients with differentiated thyroid carcinoma treated with Iodine-131, by micronucleus assay

Public title

Radiation protection effect of curcumin in patients with

thyroid cancer treated with 131-I

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients with differentiated thyroid cancer (follicular, papillary or mixed type) don't received destroying dose (ablative dose) of radioiodine up to now; no palpable neck mass; thyroid pathology reported there is no invasion to capsular and lymph areas and blood vessels; body scan with 131-I don’t show any functional tissue in regions other than the thyroid bed; thyroid cancer confirmed by biopsy; all patients have total thyroidectomy; TSH level before administration of radioiodine is higher than 30 IU/ML. exclusion criteria: after treatment with 131 I if there is abnormal tissue absorption of iodine in other areas of the thyroid bed; if patients after taking the first capsule of curcumin had a headache and dizziness; patient will be excluded.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor For Research, Shahid Beheshti University of Medical Sciences

Street address

Faculty of Paramedical Sciences، Darband St، Qods Sq، Tehran، Iran

City

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Postal code

198396-3113

Approval date

2015-03-15, 1393/12/24

Ethics committee reference number

SBMU.REC.1393.797

Health conditions studied

1

Description of health condition studied

differentiated thyroid carcinoma(DTC)

ICD-10 code

C73

ICD-10 code description

Malignant neoplasm of thyroid gland

Primary outcomes

1

Description

MN counts in 1000 BN cells

Timepoint

before and 7 days after radioiodine therapy

Method of measurement

blood sampling

Secondary outcomes

1

Description

Lymphocyte and platelets count

Timepoint

before and 1 week after radioiodine therapy

Method of measurement

blood sample/ CBC

Intervention groups

1

Description

Group I: Nano-curcumin tablets, 80 mg orally, twice daily, for 10 days from 3 days before to seven days after radioiodine therapy

Category

Treatment - Drugs

2

Description

Group II: No nano-curcumin tablets

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Center, Taleghani Hospital

Full name of responsible person

Dr. Babak Shafiei
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Velenjak St, Shahid Chamran Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mohsen Bakhshandeh
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Darband St, Qods Sq, Paramedical Department
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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, Shahid Beheshti University of Medical Sciences
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

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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