

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

###### Name

Maryam Farhadi

###### Name of organization / entity

Shahid Beheshti University of Medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2387 2206

###### Email address

maryam.farhadi@sbmu.ac.ir

##### 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

SBMU.REC.1393.797

## 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

Tehran

##### Postal code

198396-3113

#### Approval date

2015-03-15, 1393/12/24

#### Ethics committee reference number

## 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

**Street address**

Velenjak St, Shahid Chamran Highway

**City**

Tehran

**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

**Street address**

Darband St, Qods Sq, Paramedical Department

**City**

Tehran

**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**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Dr. Mohsen Bakhshandeh

**Position**

Medical Physic Phd

**Other areas of specialty/work**

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**Full name of responsible person**

Maryam Farhadi

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Ms Student of Radiobiology and Radiation Protection

**Other areas of specialty/work**

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**Person responsible for updating data**

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Maryam Farhadi

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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*