

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Radioprotective effect of melatonin in hyperthyroid patients treated by iodine-131

Protocol summary

Summary

In this experimental single blind study, for assessment of the radioprotective effect of melatonin, 60 right-handed females with O+ blood-group, who receive 12 mCi iodine-131 for hyperthyroidism treatment, will be included. Patients will be randomly divided into two groups. The first group receives one capsule containing 300 mg of melatonin powder orally, 1 hour before administration of radioactive iodine. The second group receive placebo, 1 hour before administration of radioactive iodine. For both groups, blood samples will be taken just before receiving iodine and also 1 hour after. Blood lymphocytes will be assessed by micro-nuclei test for the evaluation of chromosomal damages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090419045N1**

Registration date: **2014-10-07, 1393/07/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-07, 1393/07/15

Registrant information

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Soudabe Alidadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2016-03-18, 1394/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radioprotective effect of melatonin in hyperthyroid patients treated by iodine-131

Public title

Radioprotective effect of melatonin for hyperthyroidism treatment with iodine-131

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: female; right-handed; blood group: O+; receiving 12 mCi iodine-131 Exclusion criteria: individuals who have genetic disorders ,cancer or chemical injuries; smokers; radiation workers; and patients undergoing chemotherapy

Age

From **30 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

University of Medical Sciences, Babol

City

Babol

Postal code

41367-47176

Approval date

2014-08-16, 1393/05/25

Ethics committee reference number

304447/پ/ژ

Health conditions studied

1

Description of health condition studied

Hyperthyroidism

ICD-10 code

E00-E07

ICD-10 code description

Disorders of thyroid gland

2

Description of health condition studied

Radiation damages

ICD-10 code

W88

ICD-10 code description

Exposure to ionizing radiation

Primary outcomes

1

Description

Micronuclei frequency

Timepoint

Just before iodine-131 administration; and also 1 hour after that

Method of measurement

Cytokinesis blocked micronuclei assessment

Secondary outcomes

1

Description

Thyroid gland function

Timepoint

Before intervention; and 3 months after

Method of measurement

TSH, T4 and T3 level in blood samples

Intervention groups

1

Description

Administration of a capsule containing 300 mg of melatonin powder

Category

Prevention

2

Description

Administration of a capsule containing glucose powder

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Department, Shahid Beheshti Hospital

Full name of responsible person

Dr. Amir Gholami

Street address

Nuclear Medicine Department, Shahid Beheshti Hospital, Babol University of Medical Sciences, Babol, Iran

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2

Recruitment center

Name of recruitment center

Alborz Nuclear Medicine Center

Full name of responsible person

Dr. Mehrangiz Amiri

Street address

Sardaran 2 St., Babol, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Aliakbar Moghadamnia

Street address

Babol University of Medical Sciences, Babol, Iran

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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

Babol 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

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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