Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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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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/ژ/پ

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
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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
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Sponsors / Funding sources

1

Sponsor
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Babol University of Medical Sciences
Full name of responsible person
Dr. Aliakbar Moghadamnia
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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

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