

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Long-term Continuous Methimazole or Radioiodine Treatment for Hyperthyroidism

Protocol summary

Study aim

The aim of this study is to investigate the effectiveness of two different regimens of continuous Methimazole treatment in comparison to radioactive iodine and to compare health status, and results of neuro-psychological testing in patients receiving long-term continuous Methimazole to those of patients on replacement thyroxine doses following radioiodine-induced hypothyroidism.

Design

Patients will be assigned to the respective groups and samples will be obtained at baseline. The radio-iodine group patients will be followed up every 12 months for the duration of treatment. Patients in the "Methimazole" group will further be randomly assigned to either "Conventional Length" or "Long-term" groups and will be followed up every 6 months.

Settings and conduct

Consecutive patients with untreated first episodes of Graves' hyperthyroidism who fulfill the inclusion criteria and do not have any of the exclusion criteria are recruited from among those who present to an expert private clinic in Tehran over the span of the trial. After allocation to respective groups, the patients will be followed up according to the respective protocol.

Participants/Inclusion and exclusion criteria

A minimum of 239 patients with diffuse toxic goiter who experience recurrence of hyperthyroidism and are referred to an expert private clinic are recruited.

Intervention groups

"Radioactive Iodine Group" and "Methimazole Group". Under the "Methimazole Group" there are two more groups: "Conventional Group" and "Long-term" groups.

Main outcome variables

The primary endpoint is relapse of overt hyperthyroidism after methimazole or radioiodine discontinuation. Key secondary endpoints are occurrence of subclinical hyperthyroidism or overt or subclinical hypothyroidism during or after the treatment modality received.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201009224794N1**

Registration date: **2010-10-25, 1389/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**

Update count: **1**

Registration date

2010-10-25, 1389/08/03

Registrant information

Name

Fereidoun Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 9309

Email address

azizi@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental: Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

1990-03-01, 1368/12/10

Expected recruitment end date

2009-07-01, 1388/04/10

Actual recruitment start date

1990-03-01, 1368/12/10

Actual recruitment end date

2012-03-02, 1390/12/12

Trial completion date

2017-03-10, 1395/12/20

Scientific title

Long-term Continuous Methimazole or Radioiodine
Treatment for Hyperthyroidism

Public title

Long-term Continuous Methimazole or Radioiodine
Treatment for Hyperthyroidism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 19 years Biochemically defined overt
hyperthyroidism No history or evidence of cardiovascular
diseases No history or evidence of chronic heart failure
No history or evidence of chronic kidney disease No
history or evidence of cirrhosis

Exclusion criteria:

Evidence of pregnancy Evidence of breast-feeding
Evidence of altered mental function

Age

From **19 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **239**

Actual sample size reached: **302**

Randomization (investigator's opinion)

Randomized

Randomization description

1:1 simple randomization using the Table of Random
Digits to intervention groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The methimazole arm of the trial is further randomized
to either continue methimazole treatment for an
additional period to reach a total of 60 to 120 months
(the "long-term" group), or discontinue treatment after
the conventional period of 18 to 24 months of treatment
(the "conventional" group). This randomization is also
done through using the Table of Random Digits.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Institute for Endocrine Sciences, Shahid

Beheshti University of Medical Sciences

Street address

Next to Talegani Hospital, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2010-03-02, 1388/12/11

Ethics committee reference number

275EC

Health conditions studied**1****Description of health condition studied**

Hyperthyroidism

ICD-10 code

E05

ICD-10 code description

Thyrotoxicosis [hyperthyroidism]

2**Description of health condition studied**

anti-thyroid drugs

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Neuro-psychologic condition

Timepoint

at the beginning and end of study

Method of measurement

neuro-psychologic tests

2**Description**

Development of Goiter

Timepoint

any visit and at the end of study

Method of measurement

physical exam

3**Description**

Thyroid function assessment

Timepoint

Every 6 months during follow up and at the end of study

Method of measurement

laboratory

4

Description

Cardiac function

Timepoint

at the end of study

Method of measurement

echocardiography

Secondary outcomes

1

Description

Serum lipid profiles

Timepoint

at the beginning and end of study (during study if needed)

Method of measurement

laboratory

2

Description

bone mineral density

Timepoint

at the end of study

Method of measurement

BMD

3

Description

cost

Timepoint

During follow up and at the end of study

Method of measurement

from actual ambulatory and hospital expenses during follow up

Intervention groups

1

Description

100 µCi iodide 131 per gram of the thyroid In "radioiodine group"

Category

Treatment - Other

2

Description

Methimazole group: 10 mg of Methimazole twice daily during the first month and 10 mg daily during the second month of therapy. Maintenance doses of 2.5-10 mg daily from the third month onward.

Category

Treatment - Drugs

3

Description

"Conventional Methimazole Group": "Methimazole" for the conventional period of time, that is 18 to 24 months, as per the description provided for the main methimazole arm.

Category

Treatment - Drugs

4

Description

"Long-term Methimazole Group": "Methimazole" for a period of time in addition to the conventional period of 18 to 24 months so that the total duration of treatment with methimazole will be 60 to 120 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Azizi's Private Clinic

Full name of responsible person

Fereidoun Azizi, M.D.

Street address

Sa'aadat Abad, Riazi Bakhshayesh St., Erfan Hospital

City

Tehran

Province

Tehran

Postal code

19986

Phone

+98 21 2240 9309

Email

azizi@endocrine.ac.ir

Web page address

<http://erfanhospital.ir/en/Departments/Paraclinics/Endocrinology-Clinic>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Zadeh Vakili, PhD

Street address

Next to Taleghani Hospital, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717413

Phone

+98 21 2240 9309

Email
vakili@endocrine.ac.ir

Web page address
<http://www.endocrine.ac.ir>

Grant name
Independent Research grant

Grant code / Reference number
797

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Beheshti University of Medical Sciences

Full name of responsible person
Fereidoun Azizi, M.D.

Position
Director/ professor of Internal Medicine and Endocrinology

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology

Street address
Next to Taleghani Hospital, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717413

Phone
+98 21 2240 9309

Fax

Email
azizi@endocrine.ac.ir

Web page address
<http://www.endocrine.ac.ir>

Person responsible for general inquiries

Contact

Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fereidoun Azizi, M.D.

Position
Director

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology

Street address
Next to Taleghani Hospital, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717413

Phone
+98 21 2240 9309

Fax

Email
azizi@endocrine.ac.ir

Web page address
<http://www.endocrine.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Research Institute for Endocrine Sciences, Shahid

Person responsible for updating data

Contact

Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Miralireza Takyar, MD PhD

Position
Physician-Scientist

Latest degree
Ph.D.

Other areas of specialty/work
Internal Medicine

Street address
Next to Taleghani Hospital, Velenjak

City
Tehran

Province
Tehran

Postal code
IRAN

Phone
+98 21 2243 2500

Fax

Email
takyar@endocrine.ac.ir

Web page address
<http://www.endocrine.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified data will be shared with academic centers

and investigators for the purpose of meta-analyses.

When the data will become available and for how long

12 months after publication of the results.

To whom data/document is available

Academic investigators

Under which criteria data/document could be used

Criteria set forth by international consortia on meta-analyses and IPD-MA

From where data/document is obtainable

The Research Institute for Endocrine Sciences (RIES)

What processes are involved for a request to access data/document

Request from the PI at the RIES and approval of the legal department.

Comments