Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 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
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19986
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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
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Siences
Full name of responsible person
Fereidoun Azizi, M.D.
Position
Director
Latest degree
Subspecialist
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Director/ professor of Internal Medicine and Endocrinology
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Person responsible for updating data

Contact
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Full name of responsible person
Miralireza Takyar, MD PhD
Position
Physician-Scientist
Latest degree
Ph.D.
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Internal Medicine
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Tehran
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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 forthby 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