Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Clinical and Biochemical findings in patients with sub clinical hypothyroidism after treatment with levothyroxine

Protocol summary

Summary

The aim of this study is to assess the levothroxine effect on biochemical and clinical symptoms and signs related to hypothyroidism. Patients with subclinical hypothyroidism will be recruited in the study. Exclusion criteria are: clinical hypothyroidism, Pregnancy; thyroid or anti-thyroid medication till 1 month before study; history of coronary artery disease and arrhythmia. Thirty patients with diagnosis of subclinical hypothyroidism will be recruited from Tehran Thyroid Study. Patients will be randomly assigned in two groups (levothyroxine & placebo) for 12 months. In the intervention group , dosage will be titrated to achieve a serum TSH level between 0.3-3.5 mU/L. Main outcome measures are: systolic and diastolic blood pressure, Body Mass Index, clinical hypothyroidism scores based on modified Bilewicks questionnaire, psychomotor tests and serum concentration of thyroid antibodies, lipids, apo-lipoproteines A and B, paraxonase, prolactin, sex hormone binding globulin(SHBG), CPK, calcium, phosphorus, alkaline phosphatase and sodium before and after treatment. At the end of study data will be compared in each groups and between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103156027N1**
Registration date: **2011-05-16, 1390/02/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-16, 1390/02/26

Registrant information

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Sedigheh Moradi
Name of organization / entity
Tehran university of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Endocrine and Metabolism Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2000-07-31, 1379/05/10

Expected recruitment end date

2002-01-30, 1380/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and Biochemical findings in patients with sub clinical hypothyroidism after treatment with levothyroxine

Public title

Levothyroxine therapy in sub clinical hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with subclinical hypothyroidism Exclusion criteria: Clinical hypothyroidism; Pregnancy; thyroid or Anti-thyroid medication till 1 month before study; history of coronary

artery disease and arrhythmia and non cooperative patients

Age
From **17 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Endocrine and Metabolism research center of Shahid Beheshti University of Medical Sciences

Street address
Taleghani Hospital, Yaman st.

City
Tehran

Postal code

Approval date
2000-06-21, 1379/04/01

Ethics committee reference number
522

Health conditions studied

1

Description of health condition studied
Subclinical Hypothyroidism

ICD-10 code
E02

ICD-10 code description
Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description
Thyroid Stimulating Hormone

Timepoint
At the begining, 6 weeks after and then every 3 mo

Method of measurement
IRMA method

Secondary outcomes

1

Description
Sex hormone binding globulin(SHBG)

Timepoint
Baseline and at the end of study

Method of measurement
Radio Immuno Assay

2

Description
Creatin Phospho Kinase(CPK)

Timepoint
Baseline and at the end of study

Method of measurement
Enzymatic Colorimetry

3

Description
Body mass index(BMI)

Timepoint
Baseline and at the end of study

Method of measurement
Calculation: Weight(kg)/Height2(m)

4

Description
Hypothyroidism clinical score

Timepoint
Baseline and at the end of study

Method of measurement
Modified Bilewicz questionnaire

5

Description
Psychomotor tests

Timepoint
Baseline and at the end of study

Method of measurement
Coughlan, Ravon and Hospital anexiety depression scales(HADS) tests

6

Description
Serum concentration of thyroid antibodies

Timepoint
Baseline and at the end of study

Method of measurement
Radio Immuno Assay(RIA)

7

Description
lipids
Timepoint
Baseline and at the end of study
Method of measurement
Enzymatic colorimetry

8

Description
Apolipoproteines A and B
Timepoint
Baseline and at the end of study
Method of measurement
Torbidometry

9

Description
Paraxonase
Timepoint
Baseline and at the end of study
Method of measurement
Spectrophotometry

10

Description
Prolactin
Timepoint
Baseline and at the end of study
Method of measurement
Radio Immuno Assay

11

Description
Calcium
Timepoint
Baseline and at the end of study
Method of measurement
Chemical colorimetry

12

Description
Alkaline Phosphatase
Timepoint
Baseline and at the end of study
Method of measurement
Chemical colorimetry

13

Description
Sodium
Timepoint
Baseline and at the end of study
Method of measurement
Flame Photometry

14

Description
Phosphorous
Timepoint
Baseline and at the end of study
Method of measurement
Chemical colorimetry

15

Description
Lipoprotein A
Timepoint
Baseline and at the end of study
Method of measurement
Autoanalysis

16

Description
Systolic and Diastolic blood pressure
Timepoint
At baselina and at the end of study
Method of measurement
Standard method in Mm/Hg

Intervention groups

1

Description
Levothyroxine in active group with dose adjustment to achieve a serum TSH level between 0.3-3.5 mU/L. Levothyroxine will be used by oral in fasting state for 12 months
Category
Treatment - Drugs

2

Description
Placebo in control group, 1 tablet daily by oral root in fasting state for 12 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine and metabolism research center of Shahid Beheshti university of medical sciences
Full name of responsible person
DR Fereidoun Azizi
Street address
Taleghani HOS, Yaman st
City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Endocrine and Metabolism research center of shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Fereidoun Azizi

Street address
Endocrine and Metabolism research center, Taleghani HOS, Yaman St.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Endocrine and Metabolism research center of 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
Tehran University of Medical Sciences

Full name of responsible person
Sedigheh Moradi

Position
Assistant professor of Tehran University of Medical Sciences

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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