

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 levothyroxine 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-lipoproteins 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

Name

Sedigheh Moradi

Name of organization / entity

Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 5247

Email address

s-moradi@tums.ac.ir

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 anxiety 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
Apolipoproteins A and B

Timepoint
Baseline and at the end of study

Method of measurement
Turbidometry

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 baseline 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 route 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

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

Other areas of specialty/work

Street address

Endocrine and metabolism research center, Firouzgar HOS, Behafarin st

City

Tehran

Postal code

Phone

+98 21 8894 5247

Fax

Email

s-moradi@tums.ac.ir

Web page address

Person responsible for scientific 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

Other areas of specialty/work

Street address

Institute of Endocrine & Metabolism research center, Firouzgar HoS, Behafarin st.

City

Tehran

Postal code

Phone

+98 21 8894 5247

Fax

Email

s-moradi@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sedigheh Moradi

Position

Assistant professor, Tehran University of Medical Sciences

Other areas of specialty/work

Street address

endocrine and metabolism research center, Firouzgar HOS, Behafarin st.

City

Tehran

Postal code

Phone

+98 21889445247

Fax

Email

s-moradi@tums.ac.ir

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