

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effects of levothyroxine treatment on fat profile and adult thyroid tests with subclinical hypothyroidism referred to Imam Hossein Hospital

Protocol summary

Study aim

Evaluation of therapeutic benefits of levothyroxine on lipid profile of patients with subclinical hypothyroidism

Design

Clinical trial with control group, with parallel groups, three-sided, randomized, on 60 patients

Settings and conduct

This study is an interventional study (clinical trial) that is performed on adults aged 18 to 50 years with subclinical hypothyroidism and referred to the endocrine clinic, to confirm the diagnosis of patients, before and after confirmation. Initially, patients are re-evaluated for TSH levels after one week. In this study, which is a three-blind clinical trial study, 60 patients with newly diagnosed subclinical hypothyroidism (not yet treated) are included in the study and matched in two groups in terms of age and sex. Are divided into intervention and control groups. After obtaining informed consent, the researcher completes a basic information questionnaire and patients enter the study. In order to be randomized in this evaluation, the random number table method will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults 18 to 50 years with sub clinically confirmed hypothyroidism, consent to participate in the evaluation, no previous treatment with levothyroxine
Exclusion criteria : systemic heart, kidney and liver diseases, use of anti thyroid and lithium drugs, radiation therapy or thyroid surgery, pregnancy and central disorder (pituitary gland)

Intervention groups

Intervention group 1: They receive levothyroxine and the level of fat profile and thyroid tests are checked after a period of six months. Intervention group two: receive a placebo and the level of fat profile and thyroid tests are checked after a period of six months.

Main outcome variables

The primary outcome evaluated in this study is the laboratory status of lipid profiles and thyroid function tests.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200731048259N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Seyede Tahere Mirsamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4275 3404

Email address

sarajm13@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of levothyroxine treatment on fat profile and adult thyroid tests with subclinical hypothyroidism referred to Imam Hossein Hospital

Public title

Evaluation of the effect of levothyroxine in subclinical hypothyroidism

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

People who have normal T4 and high TSH in their blood tests

Exclusion criteria:

Taking anti thyroid drugs and lithium Treated with radiation therapy or thyroid surgery Iodine deficiency Pregnancy Central disorder (pituitary gland)

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Study as a three-blind clinical trial It is designed in such a way that from adults aged 18 to 50 years with sub clinical hypothyroidism and referring to the clinic, 60 patients who have just been diagnosed (have not been treated yet) are selected by the available method. Patients will be randomly assigned to the intervention and control groups based on the random number table. In using the random number table, the path will be from left to right. Even numbers will be assigned to the experimental group and individual numbers. Will be considered for assigning patients to the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants: With their consent, they choose one of the anonymous packages containing medicine or placebo. Principal Investigator: Throughout the project, it is not known which of the nodes of one or two patients in the placebo and which one received the drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences ,
Kodakiar Street , Shahid Shahriari Square, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

1399.585

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

Subclinical hypothyroidism

ICD-10 code

E02

ICD-10 code description

Sub clinical iodine-deficiency hypothyroidism

Primary outcomes**1****Description**

Percentage of people whose lipid profile is affected by levothyroxine treatment

Timepoint

At the beginning of the study And 7 days later and 3 and 6 months after taking levothyroxine

Method of measurement

Laboratory data

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, levothyroxine (made by Iran Hormone Pharmaceutical Company) is used. This drug is in the form of 50 microgram tablets and is taken daily as a tablet for six months (in patients with coronary heart disease and underweight). 50 kg of half dose, ie 25 micrograms per day is used)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Seyedeh Tahereh Mirsamdi

Street address

After Shahid Madani subway ,Shahid Madani Street

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Fax

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info@ehmc.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Yemen St. - Shahid Arabi St. next to Ayatollah Taleghani Hospital, Shahid Chamran Highway

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyede Tahere Mirsamadi

Position

Resident of Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Data on the main outcome can be published

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It can be used for scientific research and by submitting an application

From where data/document is obtainable

Dr. Seyedeh Tahereh Mirsamadi Email address:
doctor.mirsamadi@gmail.com

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

The request should be sent to the mentioned email address and then the required data will be provided to the applicant

Comments