Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

City
تهران

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Fax

Email
info@ehmc.ir

Web page address
https://www.ehmc.ir

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

City
تهران

Province
Tehran

Postal code
1985717443

Phone
+98 21 2387 1000

Email
info@sbmu.ac.ir

Web page address
https://www.sbmu.ac.ir/

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

Street address
Unit 6, Block 9, Narges 3,Imam Khomeini Town, Babaei Highway, Tehran

City
Tehran

Province
Tehran

Postal code
7654321879

Phone
+98 13 4275 3404

Fax

Email
sarajm13@gmail.com

Person responsible for scientific 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

Street address

Unit 6, Block 9, Narges 3,Imam Khomeini Town, Babaei Highway, Tehran

City
Tehran

Province
Tehran

Postal code
8765432109

Phone
+98 13 4275 3404

Fax

Email
sarajm13@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyede Tahere Mirsamadi

Position
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7654321890

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Fax

Email
sarajm13@gmail.com

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