

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of levothyroxine on serum lipids in patients with subclinical hypothyroidism

Protocol summary

Summary

In this randomized clinical trial, 80 subclinical hypothyroidism patients with normal serum concentrations of FT4 and TSH range of 5.2-10 mIU/L referring to endocrine clinic of Shahid Beheshti Hospital of Qom are studied. Then the patients are randomly divided into control and case groups. For the case group, levothyroxine treatment will be initiated and the control group will receive no medications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051417686N1**
Registration date: **2014-08-29, 1393/06/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-29, 1393/06/07

Registrant information

Name

Mahmoud Parham

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2949

Email address

drparham@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of levothyroxine on serum lipids in patients with subclinical hypothyroidism

Public title

Effect of levothyroxine on serum lipids in patients with subclinical hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: subclinical hypothyroidism; Exclusion criteria: TSH > 10 mIU/L; pregnancy; hyperlipidemia; serum anti-TPO Ab positivity; goiter; diabetes mellitus; ischemic heart disease.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qom University of Medical Sciences

Street address

Qom- Saheli Streeet-Qom University of Medical Sciences

City

Qom

Postal code

3719764799

Approval date

2012-10-10, 1391/07/19

Ethics committee reference number

11235/34/پ

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description

LDL

Timepoint

0 and 3 months later

Method of measurement

mg/dL

2

Description

HDL

Timepoint

0 and 3 months later

Method of measurement

mg/dL

3

Description

TG

Timepoint

0 and 3 months later

Method of measurement

mg/dL

4

Description

TSH

Timepoint

0 and 3 months later

Method of measurement

mIU/L

5

Description

T4

Timepoint

0 and 3 months later

Method of measurement

ng/dL

6

Description

Cholesterol

Timepoint

0 and 3 months later

Method of measurement

mg/dL

Secondary outcomes

empty

Intervention groups

1

Description

In the case group Levothyroxine sodium (brand name Levoxin) tablet manufactured by Iran hormone pharmaceutical company with dose of 50 microgramg is used once a day for 3 months

Category

Treatment - Drugs

2

Description

No intervention is done in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Qom

Full name of responsible person

Mahmoud Parham

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd.,
Qom-Iran

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd.,
Qom-Iran

City

Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qom 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

Qom University of Medical Sciences

Full name of responsible person

Mahmoud Parham

Position

Endocrinologist-Associate Professor

Other areas of specialty/work

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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