Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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