

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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 Street-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**

**Street address**

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drparham@muq.ac.ir

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#### Person responsible for scientific inquiries

#### Contact

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Qom University of Medical Sciences

**Full name of responsible person**

Mahmoud Parham

**Position**

Associate professor

**Other areas of specialty/work**

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#### Person responsible for updating data

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**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*