# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 2026

## Effects of Levothyroxine treatment on lipid profile in subclinical hypothyroidism

## Protocol summary

**Summary**

The purpose of this study is to investigate the effect of Levothyroxine on the serum lipids in subclinical hypothyroidism. A total of 90 patients with subclinical hypothyroidism referred to the Taleghani hospital in Kermanshah were recruited and randomly assigned into the intervention or control group. The patients in the intervention group received levothyroxine, 75 microgram in the patients with weight more than 60 and 50 microgram with weight less than 60, for three months. The patients in the control group received the same placebo with the same dose and duration. Lipid profile was measured before and after the trial and the changes were compared between groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138903244179N1**
Registration date: **2010-10-14, 1389/07/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2010-10-14, 1389/07/22

**Registrant information**

**Name**

Karoon Shahebrahimi

**Name of organization / entity**

Kermanshah Univesity of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 83 1427 6303

**Email address**

k-shahebrahimi@kums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

**Expected recruitment start date**

2010-05-22, 1389/03/01

**Expected recruitment end date**

2010-12-22, 1389/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of Levothyroxine treatment on lipid profile in subclinical hypothyroidism

**Public title**

Effects of Levothyroxine on lipid profile in subclinical hypothyroidism

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: High TSH with FT4 in normal range
Exclusion criteria: receiving levothyroxine, glucocorticoids, asprin, amiodaron, lipid lowering agents, OCP, dopamine antagonist eg. metoclopramide or domperidone in 6 months prior to the study, presence of diabetes mellitus, pregnancy, menopause, age older than 60 years

**Age**

From **14 years** old to **60 years** old

**Gender**

Both

**Phase**

4
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Kermanshah University of Medical Sciences and Health Servises
**Street address**
Shahid Beheshti boulevard, Kermanshah
**City**
Kermanshah
**Postal code**
**Approval date**
empty
**Ethics committee reference number**
7/420/5358/p

## Health conditions studied

### 1

**Description of health condition studied**
Subclinicsl Hypothyroidism
**ICD-10 code**
E02
**ICD-10 code description**
Subclinical iodine-deficiency hypothyroidism

## Primary outcomes

### 1

**Description**
triglyceride
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
photometery

### 2

**Description**
cholestrol
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
photometery

### 3

**Description**
LDL
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
photometery

### 4

**Description**
HDL
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
photometery

### 5

**Description**
lp(a)
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
biochemistry

## Secondary outcomes

### 1

**Description**
TSH
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
chemiluminescence

### 2

**Description**
FT4
**Timepoint**
Baseline and 3 months after the intervention
**Method of measurement**
chemiluminescence

## Intervention groups

### 1

**Description**
Levothyroxine 50-75 microgram daily/ orally for 3 months

**Category**
Treatment - Drugs

**2**

**Description**
Placebo 1/2- 3/4 tab daily/ orally
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Diabetic disease center of Taleghani hospital
**Full name of responsible person**
Dr. Tahere Sadat Kalantarian
**Street address**
Emam Reza Hospital, Sorkhelijeh, Kermanshah
**City**
Kermanshah

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Dr Farid Najafi
**Street address**
Shahid Beheshti boulevard, Kermanshah
**City**
Kermanshah
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kermanshah 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**
Emam Reza hospital
**Full name of responsible person**
Dr. Karoon Shahebrahimi
**Position**
Fellowship of adult's endocrine and metabolic disease
**Other areas of specialty/work**
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**Web page address**

## Person responsible for scientific inquiries

**Contact**
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Kermanshah University of Medical Science
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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Tahere Sadat Kalantarian
**Position**
Internal Medicine Resident
**Other areas of specialty/work**
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**Phone**
**Fax**
**Email**
t.kalantarian@gmail.com
**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*