

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effects of Levothyroxine treatment on lipid profile in subclinical hypothyroidism

Protocol summary

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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.

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

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 University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6303

Email address

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, aspirin, 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 Services

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

Subclinical 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

photometry

2

Description

cholesterol

Timepoint

Baseline and 3 months after the intervention

Method of measurement

photometry

3

Description

LDL

Timepoint

Baseline and 3 months after the intervention

Method of measurement

photometry

4

Description

HDL

Timepoint

Baseline and 3 months after the intervention

Method of measurement

photometry

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**Street address**

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dr-Shahebrahimi@Yahoo.Com

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Kermanshah University of Medical Science

Full name of responsible person

Karoon Shahebrahimi

Position

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Kermanshah University of Medical Sciences

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Tahere Sadat Kalantarian

Position

Internal Medicine Resident

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Emam Reza Hospital, Sorkhelijeh, Kermanshah

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Postal code**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