Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Karoon Shahebrahimi
Name of organization / entity
Kermanshah Univesity of Medical Sciences
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Iran (Islamic Republic of)
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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
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Person responsible for updating data

Contact
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Kermanshah University of Medical Sciences
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Tahere Sadat Kalantarian
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Other areas of specialty/work
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Emam Reza Hospital, Sorkhelijeh, Kermanshah
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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