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

Name
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
Fellowship of adult's endocrine and metabolic disease
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
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Tahere Sadat Kalantarian
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Internal Medicine Resident
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