Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Levothyroxine Replacement on Serum Lipid Profile in Adults With Subclinical Hypothyroidism: A Prospective Interventional Study

Protocol summary

Study aim

To evaluate the effect of levothyroxine on serum lipid profile in adults with subclinical hypothyroidism. LDL-C, total cholesterol, triglycerides and HDL-C will be assessed at baseline and 12 weeks.

Design

Prospective, single-arm, interventional study conducted at the Department of Medicine, CMH Hyderabad. Participants will undergo baseline assessment before initiation of levothyroxine therapy and will be followed for 12 weeks with predefined clinical and laboratory assessments.

Settings and conduct

Following approval from the Institutional Ethical Review Committee of CMH Hyderabad and prospective registration of the study, eligible participants will be recruited from the Department of Medicine. Participants will undergo baseline clinical assessment and laboratory investigations before initiation of treatment and will subsequently be assessed at predefined follow-up visits. Confidentiality and secure handling of participant data will be maintained according to institutional requirements.

Participants/Inclusion and exclusion criteria

Adults aged 18–65 years with biochemically confirmed subclinical hypothyroidism who are eligible for levothyroxine. Exclude overt thyroid dysfunction, previous thyroid replacement therapy, pregnancy/lactation, and inability or unwillingness to comply with treatment and follow-up.

Intervention groups

All enrolled patients received the same levothyroxine regimen of 1.6 mcg/kg/day.

Main outcome variables

Primary outcome: change in serum LDL-C, total cholesterol, triglycerides and HDL-C from baseline to 12 weeks. Secondary outcomes: change in serum TSH and time to biochemical euthyroidism.

General information

Reason for update

Acronym

LIPOTHY

IRCT registration information

IRCT registration number: **IRCT20260622069921N2**
Registration date: **2026-09-24, 1405/07/02**
Registration timing: **prospective**

Last update: **2026-09-24, 1405/07/02**
Update count: **0**

Registration date

2026-09-24, 1405/07/02

Registrant information

Name

Muhammad Ali Aslam

Name of organization / entity

Armed forces post graduate medical institute Rawalpindi

Country

Pakistan

Phone

+92 341 0441717

Email address

aliaslam187@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-10-05, 1405/07/13

Expected recruitment end date

2026-10-20, 1405/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Levothyroxine Replacement on Serum Lipid Profile in Adults With Subclinical Hypothyroidism: A Prospective Interventional Study

Public title
Changes in Serum Lipid Profile After Levothyroxine Treatment in Adults With Subclinical Hypothyroidism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult aged 18 - 65 years. Biochemically confirmed subclinical hypothyroidism, defined as elevated serum TSH with free T4 within the laboratory reference range. Patients who are willing to initiate levothyroxine therapy according to the study protocol. Patients willing to attend the scheduled follow-up visits for 12 weeks.

Exclusion criteria:
Previously diagnosed overt hypothyroidism or hyperthyroidism. Previous or current thyroid hormone replacement therapy. Pregnancy or lactation. Patients who decline or withdraw informed consent. Patients unable or unwilling to comply with the treatment and follow-up

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **112**
More than 1 sample in each individual
Number of samples in each individual: **2**
Venous blood sample collected at baseline and at 12 weeks for measurement of serum TSH and lipid profile (total cholesterol, LDL-C, HDL-C and triglycerides).

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Prospective single-arm interventional before-and-after study. Participants will be assessed at baseline before initiation of levothyroxine therapy and followed prospectively for 12 weeks, with predefined clinical and laboratory assessments at specified follow-up visits.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethical Committee/Institutional Review Board of CMH Hyderabad

Street address
CMH road, Saddar, Cantonment, CMH Hyderabad.

City
Hyderabad

Postal code
71110

Approval date
2026-01-01, 1404/10/11

Ethics committee reference number
No/11200/Estb

Health conditions studied

1

Description of health condition studied
Subclinical hypothyroidism is a biochemical condition characterized by an elevated serum thyroid-stimulating hormone concentration with free thyroxine concentration within the reference range. It may be associated with metabolic abnormalities, including alterations in serum lipid concentrations. This study will prospectively evaluate changes in lipid parameters following levothyroxine replacement therapy.

ICD-10 code
E03.9

ICD-10 code description
Hypothyroidism, unspecified

Primary outcomes

1

Description
Lipid Profile

Timepoint
Change in serum lipid levels at baseline (before initiation of levothyroxine therapy) and 12 weeks after initiation of therapy

Method of measurement
Fasting venous blood samples will be collected at baseline and at 12 weeks. Serum Lipid levels will be measured using the institution’s standard laboratory method.

Secondary outcomes

1

Description
Change in serum TSH concentration from baseline to 12 weeks.

Timepoint

Baseline and 12 weeks after initiation of levothyroxine therapy.

Method of measurement

Fasting venous blood samples will be collected at baseline and at 12 weeks. Serum TSH levels will be measured using the institution’s standard laboratory method.

2

Description

Time required to achieve biochemical euthyroidism, defined according to the predefined serum TSH target in the study protocol.

Timepoint

Baseline and 12 weeks after initiation of levothyroxine therapy.

Method of measurement

Fasting venous blood samples will be collected at baseline and at 12 weeks. Serum TSH levels will be measured using the institution’s standard laboratory method.

Intervention groups

1

Description

Levothyroxine sodium will be administered orally at an initial dose of 1.6 µg/kg/day according to the predefined study protocol. The medication will be taken once daily in the morning on an empty stomach with water. Dose adjustments, if required, will be made according to predefined TSH targets and documented during follow-up.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
CMH Hyderabad, Hyderabad Cantonment
Full name of responsible person
Dr. Asad Mahmood
Street address
CMH Road, Saddar, Cantonment, CMH Hyderabad
City
Hyderabad
Postal code
71110
Phone
+92 341 0441717
Email
aliaslam187@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
CMH Hyderabad
Full name of responsible person
Dr. Asad Mahmood
Street address
CMH Road, Saddar, Cantonment, CMH Hyderabad
City
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+92 341 0441717
Email
aliaslam187@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

CMH Hyderabad

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
CMH Hyderabad
Full name of responsible person
Dr. Asad Mahmood
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
CMH Road, Saddar, Cantonment, CMH Hyderabad
City
Hyderabad
Province
Sindh
Postal code
71110
Phone
+92 316 4757170
Email
asad1620@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
CMH Hyderabad

Full name of responsible person
Dania Mudassar

Position
General Dentist

Latest degree
Bachelor

Other areas of specialty/work
Dentistry

Street address
CMH Road, Saddar, Cantonment

City
Hyderabad

Province
Sindh

Postal code
71110

Phone
+92 341 5072055

Email
dania.mudassar@outlook.com

Person responsible for updating data

Contact

Name of organization / entity
CMH Hyderabad

Full name of responsible person
Dania Mudassar

Position
General Dentist

Latest degree
Bachelor

Other areas of specialty/work
Dentistry

Street address
CMH Road, Saddar, Cantonment

City
Hyderabad

Province
Sindh

Postal code
71110

Phone
+92 341 5072055

Email
dania.mudassar@outlook.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Limitations in participant consent, data sharing policy of institute and confidentiality of study participants.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available