

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Changes in serum lipid profile following six months of levothyroxine therapy in patients with subclinical hypothyroidism: a quasi-experimental study

Protocol summary

Study aim

The aim of this study is to evaluate the lipid profile level changes assessed by total serum cholesterol (TC), serum low density lipoproteins (LDLs), serum triglycerides (TGs) and serum high density lipoproteins (HDLs) after six months of levothyroxine therapy in patients with presenting with sub-clinical hypothyroidism.

Design

Pragmatic research, quasi experimental study, carried out at the Department of Medicine, Combined Military Hospital, Hyderabad from August 2025 – January 2026

Settings and conduct

After approval from the Institutional Ethical Review Committee, CMH Hyderabad, the study was conducted in the institute, ensuring strict confidentiality and data protection according to institutional and international guidelines. Simple random sampling was used to recruit a total of 90 adult patients aged 18–65 years diagnosed with mild SCH (sub-clinical hypothyroidism) (TSH 4.49–10 mIU/L) or moderate SCH (TSH >10 mIU/L) with normal T3 and T4 levels. They were screened through laboratory-verified thyroid profiles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients aged 18–65 years of age diagnosed with sub-clinical hypothyroidism (mild and moderate) as per the WHO definition criteria furnished in the methodology and planned for levothyroxine therapy for six months. Exclusion criteria: patients already on thyroid replacement therapy, Overt hypothyroidism or Hyperthyroidism, Pregnancy or lactation, use of medications significantly known to affect thyroid function or lipid metabolism (e.g amiodarone, statins)

Intervention groups

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

Main outcome variables

Primary variables studied were mean change in serum

lipid levels assessed by total serum cholesterol, serum low density lipoproteins, serum triglycerides and serum high density lipoproteins.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260622069921N1**

Registration date: **2026-06-28, 1405/04/07**

Registration timing: **retrospective**

Last update: **2026-06-28, 1405/04/07**

Update count: **0**

Registration date

2026-06-28, 1405/04/07

Registrant information

Name

Muhammad Ali Aslam

Name of organization / entity

Armed forces post graduate medical institute
Rawalpindi

Country

Pakistan

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-26, 1404/01/06

Expected recruitment end date

2026-01-01, 1404/10/11

Actual recruitment start date

2025-03-27, 1404/01/07

Actual recruitment end date

2026-01-02, 1404/10/12

Trial completion date

2026-01-05, 1404/10/15

Scientific title

Changes in serum lipid profile following six months of levothyroxine therapy in patients with subclinical hypothyroidism: a quasi-experimental study

Public title

Effect of levothyroxine therapy on serum lipid profile in patients with subclinical hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

diagnosis of subclinical hypothyroidism levothyroxine therapy planned for six months 18-65 years of age

Exclusion criteria:

Patients already on thyroid replacement therapy Overt Hypothyroidism or hyperthyroidism Pregnancy, lactation Use of medications known to significantly affect thyroid function or lipid metabolism e.g. amiodrone, statins

Age

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

Gender

Both

Phase

2-3

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: **112**

Simple random sampling was used to recruit patients diagnosed with Subclinical Hypothyroidism.

Actual sample size reached: **90**

More than 1 sample in each individual

Actual sample size in each individual: **90**

Simple random sampling was used to recruit a total of 90 adult patients aged 18-65 years diagnosed with mild SCH (sub-clinical hypothyroidism) (TSH 4.49-10 mIU/L) or moderate SCH (TSH >10 mIU/L) with normal T3 and T4 levels

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**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

2025-03-26, 1404/01/06

Ethics committee reference number

No/11105/Estb

Health conditions studied**1****Description of health condition studied**

Sub-clinical hypothyroidism (SCH) refers to the condition in which there is increase in the levels of serum TSH with normal T3 and T4 levels. While the condition does not manifest clinically in majority of the cases, it is associated with weight gain, hormonal disturbances, insulin resistance, dyslipidemia, and increased incidence of cardiac complications.

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

Primary outcomes**1****Description**

lipid profile

Timepoint

Change in serum lipid levels at baseline (before initiation of levothyroxine therapy), 12 weeks after initiation of therapy, 24 weeks after initiation of therapy

Method of measurement

Laboratory investigations - complete blood count, thyroid profile (TSH, T3, T4), and fasting lipid profile (total cholesterol, LDL, HDL, triglycerides)

Secondary outcomes**1****Description**

Secondary variables studied were time to achieve euthyroid status (based on serum TSH levels)

Timepoint

Before intervention, 12 weeks after initiation of levothyroxine therapy, 24 weeks after initiation of levothyroxine therapy

Method of measurement

Laboratory investigations including complete blood count, thyroid profile (TSH, T3, T4), and fasting lipid profile (total cholesterol, LDL, HDL, triglycerides).

Intervention groups**1****Description**

Intervention group: All enrolled participants will receive levothyroxine sodium tablets (Thyroxine tablets - Getz Pharma) administered at an initial dose of 1.6 mcg/kg/day, based body weight taken once daily in the morning on an empty stomach, at least 30-60 mins before breakfast with water. Treatment will continue for six months. Compliance will be assessed during follow up visits.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

CMH Hyderabad, Hyderabad Cantonment

Full name of responsible person

Brig. Asad Mahmood

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CMH Road, Saddar, Cantonment, CMH Hyderabad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

CMH Hyderabad

Full name of responsible person

Brig. Asad Mahmood

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

CMH Hyderabad

Full name of responsible person

Muhammad Ali Aslam

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

Independent Researcher

Full name of responsible person

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Position

General Dentist

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

Street address

CMH Road, Saddar, Cantonment

City**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