# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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+92 341 0441717

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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
**Street address**
CMH Road, Saddar, Cantonment, CMH Hyderabad
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## Sponsors / Funding sources

### 1

**Sponsor**
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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

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## Person responsible for updating data

**Contact**
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## 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