

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Non-inferiority Randomized Controlled Clinical Trial of the hormonal responses to Levothyroxin made by Aburaihan company and Levothyroxine made by Merck company

#### Protocol summary

##### Study aim

The study of clinical responses to Levothyroxine made by Abureihan versus Merck company

##### Design

This clinical trial includes two groups of hypothyroid patients. The groups are double-blinded, parallel groups, and randomized. Phase 2 consists of 60 patients.

Patients are divided into two groups based on cluster randomization

##### Settings and conduct

Patients will be recalled from a private clinic in Tehran to the Research Institute for Endocrine Sciences. The treatment will be allocated based on the pre-specified double-blinded random allocation while the researchers and patients are blinded to therapy. The drug will be continued for eight weeks. Participants will be evaluated for biochemical assessments, thyroid symptoms, and treatment satisfaction at baseline and end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: New patients with Hypothyroidism: serum TSH level should be 5.06-19.9 mIU/L and serum FT4 less than 0.91 ng/dL. Only new patients who have never taken thyroid treatment  
Exclusion criteria: Pregnant women  
People with underlying diseases such as liver failure, renal failure, heart failure  
People with co-factors that can simulate hypothyroidism symptoms: Low Hgb, Vitamin D and B12 deficiency, and Depression  
Taking any of the following medications during the trial: Methimazole, PTU, Tamoxifen, drugs containing Estrogen and Progesterone, Corticosteroid, Gastrointestinal medication

##### Intervention groups

The first group consists of 30 patients with Hypothyroidism who receive Levothyroxine pills made by Merck. The treatment begins with 1.6 micro-gram per kg daily. The second group consists of 30 patients with hypothyroidism who will receive Levothyroxine pills

made by the Abureihan company. The treatment begins with 1.6 micro-gram per kg daily.

##### Main outcome variables

The changes in serum TSH level and serum FT4 level, TSQ and THY-TSQ

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220307054211N1**

Registration date: **2022-05-15, 1401/02/25**

Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**

Update count: **0**

##### Registration date

2022-05-15, 1401/02/25

##### Registrant information

##### Name

Atieh amouzegar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2500

##### Email address

amouzegar@endocrine.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-11, 1401/04/20

##### Expected recruitment end date

2023-01-10, 1401/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Non-inferiority Randomized Controlled Clinical Trial of the hormonal responses to Levothyroxin made by Aburaihan company and Levothyroxine made by Merck company

**Public title**

Comparison of the hormonal responses to Levothyroxin made by Aburaihan company with Levothyroxine made by Merck company

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

New patients with Hypothyroidism: serum TSH level should be 5.06-19.9 mIU/L and serum FT4 less than 0.91 ng/dL. Only new patients who have never taken thyroid treatment.

**Exclusion criteria:**

Pregnant women People with underlying diseases such as liver failure, renal failure, heart failure People with co-factors that can simulate hypothyroidism symptoms: Low Hgb, Vitamin D and B12 deficiency, and Depression Taking any of the following medications during the trial: Methimazole, PTU, Tamoxifen, Drugs containing Estrogen and Progesterone, Corticosteroid, Gastrointestinal medication

**Age**

From **20 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are divided into two intervention groups based on cluster randomization. Six stratifications will be made based on age and gender. At first, patients will be assigned to three age groups of  $\leq 50$ y, 51-70y, and  $> 70$  y. Under each subgroup, patients will be assigned to male and female. Then under each sex subgroup, patients will be randomly assigned to two treatment groups using the random table. Random sequences will be generated using Random-Allocation software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After performing randomization and special coding, subjects are assigned to groups using concealment, which helps keep physicians, participants, and researchers unaware of the type of treatment being assigned. Standard methods will be used to ensure concealment. Opaque containers will be numbered or coded in order. For single-center clinical trials such as the current trial, we select an expert who does not participate in the trial and can maintain a randomized list. This person is instructed to keep the list private and disclose treatment allocation only after receiving information indicating the patient is eligible and has consented to the trial. Subjects and researchers will be protected from knowing who will be assigned to which treatment (double-blind). Both groups will receive the same pills in appearance, taste, and smell.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

The drug will be continued in 2 intervention groups (Levothyroxine made by Merck and Abureihan companies). Patients will be visited 6 and 8 weeks later to measure TSH and FT4 and assess therapy adherence and adverse effects. Drug dosage would be adjusted to maintain serum TSH concentration within 0.5-3 mU/l. Participants will be evaluated at baseline and two consequent follow-ups at six and eight weeks. At the first, second, and last visit at eight weeks, venous blood samples will be collected from all participants to measure serum TSH and FT4. Thyroid symptom questionnaires (TSQ) and thyroid treatment satisfaction questionnaires (ThyTSQ) will be filled out at the first and last visits (TSQ and ThyTSQ). To ensure compliance with drug therapy, the responsible person will check the drug package and count the number of pills intake by direct questioning in 2 weeks intervals by phone call and pill counting at the last visit.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical

**Street address**

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Yaman St, Tehran Province, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717413

**Approval date**

2022-05-07, 1401/02/17

**Ethics committee reference number**

IR.SBMU.ENDOCRINE.REC.1401.008

**Health conditions studied**

**1**

**Description of health condition studied**

Hypothyroidism

**ICD-10 code**

E03.9

**ICD-10 code description**

Hypothyroidism, unspecified

**Primary outcomes**

**1**

**Description**

Changes of serum TSH level

**Timepoint**

First day, 6 weeks and 8 weeks after intervention

**Method of measurement**

Serum TSH and FT4 will be determined on blood samples by the Electrochemiluminescence immunoassay (ECLIA) method, using Roche Diagnostics kits and Roche/Hitachi Cobas e-411 analyzer (GmbH, Mannheim, Germany).

**2**

**Description**

Changes of serum FT4 level

**Timepoint**

First day, 6 weeks and 8 weeks after intervention

**Method of measurement**

Serum TSH and FT4 will be determined on blood samples by the Electrochemiluminescence immunoassay (ECLIA) method, using Roche Diagnostics kits and Roche/Hitachi Cobas e-411 analyzer (GmbH, Mannheim, Germany).

**Secondary outcomes**

**1**

**Description**

Thyroid symptoms

**Timepoint**

At the first and last visits

**Method of measurement**

Thyroid symptom questionnaire (TSQ)

**2**

**Description**

Treatment satisfaction

**Timepoint**

At the first and last visits

**Method of measurement**

Treatment satisfaction questionnaire (THY-TSQ)

**Intervention groups**

**1**

**Description**

Intervention group number one: This group will receive Levothyroxine pills made by Merck company. They will take 1.6 micro-gram per kg daily before breakfast for eight weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group number two: This group will receive Levothyroxine pills made by Abureihan company. They will take 1.6 micro-gram per kg daily before breakfast for eight weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Atieh Amouzegar

**Street address**

No.23, Erabi St, Velenjak, Tehran, Iran

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+98 21 2241 6264

**Email**

amouzegar@endocrine.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Aburairhan pharmaceutical co.

**Full name of responsible person**

Mohammad Ahmadi

**Street address**

No.1, Khoshvaght St , Tehranpars

**City**

Tehran

**Province**

Tehran

**Postal code**  
1654613111

**Phone**  
+98 21 7770 7173

**Email**  
info@aburaihan.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Aburaihan pharmaceutical co.

**Proportion provided by this source**  
100

**Public or private sector**  
Private

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
*empty*

**Country of origin**  
**Type of organization providing the funding**  
Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Atieh Amouzegar

**Position**  
Associate professor

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
Internal Medicine

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## Person responsible for scientific inquiries

### Contact

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**Position**  
Associate professor

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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences

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**Position**  
Associate professor

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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

These data belong to Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences.

### 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