

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of the efficacy of Levothyroxine on pulmonary function tests in patients with subclinical hypothyroidism in comparison with Placebo

#### Protocol summary

##### Study aim

The efficacy of Levothyroxine on pulmonary function tests in patients with subclinical hypothyroidism

##### Design

Randomised clinical trial , Randomised to intervention and control groups ,Parallel ,Treatment purposes , Two-sided blinded ,50 samples , Each sample an individual

##### Settings and conduct

At the beginning all patients have pulmonary function tests by Spirometry Plethysmography and Ergospirometry devices. Then patients go under treatment by Levothyroxine or placebo for 12 weeks .At the end, pulmonary function tests would be repeated and re-evaluated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of subclinical hypothyroidism, age 25 to 55 years old exclusion criteria: Chronic pulmonary disease, hypertension, diabetes, chronic kidney disease, chronic heart disease , stroke, receiving heart medicine (such as amiodarone, beta-blockers and calcium blockers), smoking cigarette or shisha, critical patients, pregnancy, goiter, obesity, individuals with TSH level above 10 , individuals with a history of thoracic and abdominal surgery and Patients with any systemic disease leading to myopathy.

##### Intervention groups

Intervention group: Levothyroxine 50 Micrograms Daily  
Control group: Placebo

##### Main outcome variables

Forced expiratory volume in 1 second (FEV1) Forced vital capacity (FVC) Forced expiratory volume in 1 second / Forced vital capacity (FEV1/FVC) Peak expiratory flow rate (PEFR) Forced expiratory flow 25-75% (FEF 25-75%) Peak expiratory Flow (PEF) Diffusing capacity of the lung for carbon monoxide (DLCO) Maximal inspiratory pressure (PIMAX) Maximal expiratory pressure (PEMAX) Functional Residual Capacity (FRC) Residual Volume (RV) Total lung capacity (TLC) VO2 (reserve) Oxygen absorption rate HR (reserve) Heart rate per minute by

scale of Bpm VE: Volume of inlet or outlet gas from the lungs per minute R :The gas exchange rate  $R = \frac{V_{O_2}}{V_{CO_2}}$

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180811040767N1**

Registration date: **2018-11-30, 1397/09/09**

Registration timing: **prospective**

Last update: **2018-11-30, 1397/09/09**

Update count: **0**

##### Registration date

2018-11-30, 1397/09/09

##### Registrant information

##### Name

Khadijeh Kordi Tamandani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3343 3407

##### Email address

khadijehkordi72@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-11, 1397/09/20

##### Expected recruitment end date

2020-12-10, 1399/09/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Study of the efficacy of Levothyroxine on pulmonary function tests in patients with subclinical hypothyroidism in comparison with Placebo

**Public title**  
efficacy of Levothyroxine on pulmonary function tests in patients with subclinical hypothyroidism

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosis of subclinical hypothyroidism Minimum age of 25 years old Maximum age of 55 years old

**Exclusion criteria:**  
Chronic pulmonary disease Hypertension Diabetes Chronic kidney disease Chronic heart disease Stroke Receiving heart medicine (such as amiodarone, beta-blockers and calcium blockers) Smoking cigarette or shisha Critical patients Pregnancy Goiter obesity Individuals with TSH level above 10 Individuals with a history of thoracic and abdominal surgery Patients with any systemic disease leading to myopathy

**Age**  
From **25 years** old to **55 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization is performing by a computer generated sequence ; random numbers are considered for each participant and maintained by the PI in sealed envelopes, and the patients are distributing in 2 groups of Levothyroxine or placebo according to these numbers

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients and clinical personnel such as physicians , nurses ,physiotherapists and anyone with direct contact to patients are blinded, but researcher and evaluator and DSMB (Data Safety and Monitoring Committee) are not blinded.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

##### Street address

ZAUMS Main campus, DoctorHesabi Square , Zahedan, Sistan and Baluchestan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

#### Approval date

2018-09-29, 1397/07/07

#### Ethics committee reference number

IR.ZAUMS.REC.1397.262

## Health conditions studied

### 1

#### Description of health condition studied

subclinical hypothyroidism

#### ICD-10 code

E02

#### ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

## Primary outcomes

### 1

#### Description

Forced expiratory volume in 1 second (FEV1)

#### Timepoint

At the beginning of the study (before the intervention) and twelve weeks after the intervention

#### Method of measurement

Spirometry

### 2

#### Description

Forced vital capacity (FVC)

#### Timepoint

At the beginning of the study (before the intervention) and twelve weeks after the intervention

#### Method of measurement

Spirometry

### 3

#### Description

Forced expiratory volume in 1 second / Forced vital capacity (FEV1/FVC)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Spirometry

**4**

**Description**

Peak expiratory flow rate (PEFR)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Spirometry

**5**

**Description**

Forced expiratory flow 25-75% (FEF 25-75%)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Spirometry

**6**

**Description**

Peak expiratory Flow (PEF)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Spirometry

**7**

**Description**

Diffusing capacity of the lung for carbon monoxide (DLCO)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Plethysmography

**8**

**Description**

Maximal inspiratory pressure (PIMAX)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Plethysmography

**9**

**Description**

Maximal expiratory pressure (PEMAX)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Plethysmography

**10**

**Description**

Functional Residual Capacity (FRC)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Plethysmography

**11**

**Description**

Residual Volume (RV)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Plethysmography

**12**

**Description**

Total lung capacity (TLC)

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Plethysmography

**13**

**Description**

VO<sub>2</sub> (reserve) Oxygen absorption rate

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Ergospirometry

**14**

**Description**

HR (reserve) Heart rate per minute by scale of Bpm

**Timepoint**

At the beginning of the study (before the intervention) and twelve weeks after the intervention

**Method of measurement**

Ergospirometry

**15**

**Description**

VE: Volume of inlet or outlet gas from the lungs per minute

**Timepoint**

At the beginning of the study (before the intervention)

and twelve weeks after the intervention

#### Method of measurement

Ergospirometry

## 16

#### Description

R :The gas exchange rate  $R = \dot{V}O_2 / \dot{V}CO_2$

#### Timepoint

At the beginning of the study (before the intervention) and twelve weeks after the intervention

#### Method of measurement

Ergospirometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Name of drug :Levothyroxine 50 Micrograms Daily made in Islamic republic of Iran by Iran Hormone Company

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

بیمارستان فوق تخصصی علی ابن ابیطالب

##### Full name of responsible person

Dr.Aliреза Bakhshipur

##### Street address

Salamat Blvd., Persian Gulf Highway, Zahedan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743111

##### Phone

+98 54 3329 5564

##### Fax

+98 54 3329 5563

##### Email

enzaums.news@zaums.ac.ir

##### Web page address

http://www.alihos.zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Dr.Noor Mohammad Bakhshani

##### Street address

ZAUMS Main campus, DoctorHesabi Square , Zahedan, Sistan and Baluchestan, Iran

##### City

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##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5715

##### Email

public@zaums.ac.ir

##### Web page address

http://zaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zahedan University of Medical Sciences

#### 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

Zahedan University of Medical Sciences

##### Full name of responsible person

Khadijeh Kordi Tamandani

##### Position

Internal medicine resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

NO. 59, Adabiat Houses ,Kuie'Asatid , Daneshgah Ave ,Zahedan

##### City

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##### Province

Sistan-va-Balouchestan

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ahmad4341@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Khadijeh Kordi Tamandani

**Position**

Internal medicine resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Khadijeh Kordi Tamandani

**Position**

Internal medicine resident

**Latest degree**

Medical doctor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available