Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 = vo2 / Vco2

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 Saftey 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

VO2 (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 = vo2 / Vco2

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.Alireza 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

Zahedan

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

Zahedan

Province

Sistan-va-Balouchestan

Postal code
9816744166

Phone
+98 54 3343 3407

Email
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
Internal Medicine

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

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816744166

Phone
+98 54 3343 3407

Email
ahmad4341@gmail.com

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

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

Postal code
9816744166

Phone
+98 54 3343 3407

Email
ahmad4341@gmail.com

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