Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of a period of aerobic training on serum Insulin-like growth factor 1 levels and thyroid hormones in subclinical hypothyroidism women

Protocol summary

Summary

The purpose of the study: Insulin-like growth factor-1 hormone has an effect on physiological processes in the body. Insulin-like growth factor-1 levels decrease in patients with hypothyroidism. Therefore, the aim of this study was to investigate the effect of an aerobic period on insulin-like growth factor-1 Women with hypothyroidism are hypothyroidism. Key Entry Criteria: Women aged 30-40 years with hypothyroidism with predisposing thyroid disease, lack of specific disease (cardio-respiratory and diabetes), regular administration of 0.1 mg sodium levothyroxine tablet manufactured by Iran Hormones (For the drug-active and control group), non-alcohol and tobacco use, attend aerobic exercise sessions for both experimental groups. Key Criteria for Exit: Congenital Thyroid Disease, Pregnancy. Population and sample size: The subjects of this study were women between the ages of 30 and 42 years old with hypothyroid hypnotic hypothyroidism, whose condition was pre-determined and treated. A list of patients with hypoparathyroidism under treatment was provided by referring to the sporting halls of the city and informing them. Of the women who were volunteered to participate in the study, 16 were selected who underwent an aerobic exercise (aerobic) on a regular basis, 3 sessions in the evening, and had criteria for entering the study. Of the 16 selective individuals, 9 people who were taking levothyroxine sodium in addition to their sports activities also participated in the active group in the active-drug therapy group and 7 people who were aware of their illness but did not use levothyroxine sodium. It was noted that with the loss of 3 subjects in this group, the final number was reached to 4, and a subject from the drug-active group did not participate until the end of the study, so the volume of subjects in the drug-active group decreased to 8 and the active group was reduced to 4 persons . In the next step, 10 patients from volunteer women who had no history of taking exercise and only taking levothyroxine sodium were placed in the control group (n = 10). After completing the study, the subjects participated in the study with complete satisfaction. Study Intervention and its Time: Both groups that participated in physical activity, with an average duration of 5 months, regularly performed aerobic exercise 3 sessions per week and each session for one hour at 16:00 noon. The exercise program included: 1) 10 minutes of warming with simple movements and low intensity, which increased in the last few minutes,2) 40 minutes aerobic exercise (musical movements with music) with a minute of rest after 20 minutes and 3) 10 minutes of stretching and cooling. The movements of the aerobics consisted of moving chains that were joined by smaller movements, sometimes stepped and sometimes without stepping. More aerobic movements focused on large and multifaceted muscles, especially the legs. During the duration of the study, the drug-active and control group used regular levothyroxine sodium tablets of 0.1 mg. Primary Implications: Blood samples from the venous vein on the elbow were taken at 8 to 9 am after 10-12 hours of fasting. To remove the interim training effects, subjects were asked to avoid severe physical activity 48 hours before blood sampling. To measure serum concentrations of insulin-like growth factor-1, 5 ml of blood was taken from each person and centrifuged for 10 minutes at 2500 rpm. Separated serum was stored at -20 to -22 degrees Celsius. Serum insulin-like growth factor-1 concentrations were measured using a German IBL kit with a sensitivity of 0.09 ng / mL.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070528429N4**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2017-11-01, 1396/08/10

Registrant information
Name
Mohammd Fathi
Name of organization / entity
Lorestan University
Country
Iran (Islamic Republic of)
Phone
+98 916 397 2041
Email address
fathi.m@lu.ac.ir

Recruitment status
Recruitment complete
Funding source
Investigator

Expected recruitment start date
2016-04-20, 1395/02/01
Expected recruitment end date
2016-09-24, 1395/07/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of a period of aerobic training on serum Insulin-like growth factor 1 levels and thyroid hormones in subclinical hypothyroidism women

Public title
The effect of exercise on hormones
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: 30-49 year-old women with hypothyroidism with predetermined disease; No specific disease (cardio-respiratory and diabetes); Regular use of 0.1 mg levothyroxine tablets Iran Hormones Inc. (for the drug-exercise and control groups); No alcohol and tobacco use; Participation in aerobic exercise sessions for both experimental groups. Exclusion criteria: Obese affliction of thyroid disease; Pregnancy
Age
From **30 years** old to **42 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lorestan University of Medical Sciences Ethics Committee
Street address
University of Medical Sciences, Shahid Anoushirvan Rezaie Square, Moalem Street, Khoram Abad, Lorestan Province
City
Khoramabad
Postal code
Approval date
2017-10-23, 1396/08/01
Ethics committee reference number
IR.LUM.REC.1396.312

Health conditions studied

1

Description of health condition studied
Hypothyroidism
ICD-10 code
E02
ICD-10 code description
Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description
Insulin-like growth factor 1
Timepoint
48 hours after the last training session
Method of measurement
Blood sampling

Secondary outcomes

1

Description

Thyroid hormones

Timepoint

48 hours after the last training session

Method of measurement

Blood sampling

Intervention groups

1

Description

"drug-exercise group: taking levothyroxine sodium tablet 0.1 mg per day one day before breakfast for 5 months, performing aerobic activity three sessions per week each session one hour at 16 noon for 5 months."

Category

Prevention

2

Description

"exercise group: Aerobic exercise three sessions per week per session one hour at 16:00 for 5 months without taking levothyroxine sodium 0.1 mg."

Category

Prevention

3

Description

"Control group: taking levothyroxine sodium 0.1 mg as One day before breakfast for 5 months, without physical activity."

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University

Full name of responsible person

Mohammad Fathi

Street address

Department of Physical Education and Sport Sciences, Lorestan University, 5th kilometer road of Tehran, Khorram Abad, Lorestan Province

City

Khoramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Mohammad Fathi

Street address

Department of Physical Education and Sport Sciences, Lorestan University, 5th kilometer road of Tehran, Khoram Abad, Lorestan Province

City

Khoramabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Lorestan University

Full name of responsible person

Mohammad Fathi

Position

Assistant Professor and Faculty Member of Lorestan University

Other areas of specialty/work

Street address

Department of Physical Education and Sport Sciences, Lorestan University, 5th kilometer road of Tehran, Khorram Abad, Lorestan Province

City

Khoramabad

Postal code

44316-68151

Phone

+98 916 397 2041

Fax

+98 33120104

Email

javidfathi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lorestan University

Full name of responsible person

Mohammad Fathi

Position

Assistant Professor and Faculty Member of Lorestan University

Other areas of specialty/work
Street address
Department of Physical Education and Sport Sciences, Lorestan University, 5th kilometer road of Tehran, Khorram Abad, Lorestan Province
City
Khoramabad
Postal code
44316-68151
Phone
+98 916 397 2041
Fax
+98 33120104
Email
javidfathi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Lorestan University
Full name of responsible person
Mohammad Fathi
Position
Assistant Professor and Faculty Member of Lorestan University
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Street address
Department of Physical Education and Sport Sciences, Lorestan University, 5th kilometer road of Tehran, Khorram Abad, Lorestan Province
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Phone
+98 916 397 2041
Fax
+98 33120104
Email
javidfathi@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty