

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of one session of Aerobic Discontinuous Training protocol on Hepcidin and plasma Ferritin in patients with Beta Thalassemia Intermedia

Protocol summary

Summary

Purpose of this study is to determine the effect of one session of Aerobic Discontinuous Training protocol with 65% heart rate reserve intensity on Hepcidin and plasma Ferritin in patients with Beta Thalassemia Intermedia. This study is semi-experimental with the experimental and control groups that will be run as pre and post-test. Twenty Beta Thalassemia Intermedia patients with Ejection fraction higher than 55%, and lower pulmonary artery pressure of 30 mm Hg and no history of heart disease with irregular blood transfusions or no blood transfusions will take part in this study. After determine eligibility for patients entry in study, in the form who are fasting refer to lab to take prototype. After that the patients take part in 10 minutes warm up include general and special movements such as running and Stretching. Then, each patient in the form single will done 3 period of 10 minutes running with 5 minutes of disabled rest between each period that monitor with cardiac screening to run with 65% heart rate reserve. Immediately and 3 hours after the workout the next blood samples will be obtained.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062516211N2**
Registration date: **2015-07-11, 1394/04/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-11, 1394/04/20

Registrant information

Name

Majid Mohabbat

Name of organization / entity

Education

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical sciences and State Resources

Expected recruitment start date

2015-07-01, 1394/04/10

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of one session of Aerobic Discontinuous Training protocol on Hepcidin and plasma Ferritin in patients with Beta Thalassemia Intermedia

Public title

The effect of exercise on main iron regulator hormone in patients with Beta Thalassemia Intermedia

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: 1-Patients with Beta Thalassemia

Intermedia. 2-Irregular blood transfusions or no blood transfusions. 3-Ejection Fraction more than 55%. 4- Pulmonary artery pressure or (PAP) less than of 30 mm Hg. 5-Lack of Hemochromatosis. 6-The absence of fractures in lower limbs. 7-Lack of diabetes. Exclusion criteria: 1-Regular blood transfusions. 2-Iron overload in the heart. 3-Splenectomized patients. 4-Drugs such as Digoxin and other drugs associated with heart disease. 5-Personal desire, nausea, vomiting and headache during exercise.

Age

From **31 years** old to **48 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

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

Baqiyatallah University of Medical sciences

Street address

Baqiyatallah University of Medical Sciences, Vanak Square, Sheikh Bahai St, Tehran, Iran

City

Tehran

Postal code

Iran

Approval date

2014-11-02, 1393/08/11

Ethics committee reference number

340/5/5904/س

Health conditions studied

1

Description of health condition studied

Beta Thalassemia Intermedia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Hepcidin

Timepoint

Before, immediately after and 3 hours after the intervention.

Method of measurement

Blood sample and ELISA method

2

Description

Ferritin

Timepoint

Before, immediately after and 3 hours after the intervention.

Method of measurement

Blood sample and Photometric method

Secondary outcomes

1

Description

24-hour dietary recall

Timepoint

24 hour before primary blood sample

Method of measurement

By 24-hour dietary recall questionnaire

2

Description

Blood pressure

Timepoint

Before and after each period of practice

Method of measurement

By manual manometer and according to mm Hg

3

Description

RPE or Rate of Perception Effort

Timepoint

Before and after each period of practice

Method of measurement

20-point Borg questionnaire

Intervention groups

1

Description

Control Group will be among those who did not have

regular physical activity in the past six months.

Category

N/A

2

Description

The exercise group after the 10-minute warm-up in three 10-minute periods with 65% heart rate reserve run on the treadmill. Before and after each 10-minute period RPE is measured by using the Borg index.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Zafar Adult Thalassemia Clinic

Full name of responsible person

Azita azarkeivan

Street address

No. 1 Shariati St., St. Zafar, north of M. Nasiri Street in Front of shahin St,Zargandeh Plumbing,Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Exercise Physiology Research Center,Baqiyatallah University of Medical Sciences Baqiyatallah

Full name of responsible person

Vahid Sobhani

Street address

Baqiyatallah University of Medical Sciences,Vanak Square, Sheikh Bahaii St, Tehran, Iran

City

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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

Exercise Physiology Research Center,Baqiyatallah University of Medical Sciences Baqiyatallah

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

Baqiyatallah University of Medical Sciences,Exercise Physiology Research Center

Full name of responsible person

Vahid Sobhani

Position

Head of Department/Ph.D

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Person responsible for scientific inquiries

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Education

Full name of responsible person

Majid Mohabbat

Position

Master of science

Other areas of specialty/work

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Education

Full name of responsible person

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Position

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Other areas of specialty/work

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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