

# 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)

##### Phone

+98 28 3334 9035

##### Email address

m.mohabbat@srttu.edu

##### 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**

Tehran

**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

**Other areas of specialty/work**

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Education

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Majid Mohabbat

**Position**

Master of science

**Other areas of specialty/work**

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**Full name of responsible person**

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**Fax****Email**

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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*