

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Study of the effect of resistance-aerobic training on cardiovascular index, quality of life, body composition and physical fitness in beta thalassemia major patients

#### Protocol summary

##### Study aim

Assessing the effect of resistance- aerobic training on cardiovascular index, quality of life, body composition and physical fitness in beta thalassemia major patients

##### Design

Randomize clinical trail with parallel groups, non blinded, conducted between April and June of 2016

##### Settings and conduct

This clinical trial study was conducted between April and June of 2016 in Thalassemia department of Shahid Amini hospital of Langarud and the participants were randomly divided into two experimental and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patient with beta thalassemia major disease, whom have regular blood transfusion, as well as a history of Desferal usage (19–25 years) Exclusion criteria: have an acute heart disease and any abnormalities, which can limit exercise

##### Intervention groups

Experimental group: in addition to the usual treatment, they will be done 2-3 sessions of incremental resistance-aerobic training per week for six weeks Control group: only the usual treatment will be done for them

##### Main outcome variables

Cardiovascular index; quality of life; body composition; physical fitness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150531022498N19**

Registration date: **2018-03-18, 1396/12/27**

Registration timing: **retrospective**

Last update: **2018-03-18, 1396/12/27**

Update count: **0**

##### Registration date

2018-03-18, 1396/12/27

##### Registrant information

###### Name

Ramin Shabani

###### Name of organization / entity

Islamic Azad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3375 2715

###### Email address

shabani@iaurasht.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-02-19, 1394/11/30

##### Expected recruitment end date

2016-03-09, 1394/12/19

##### Actual recruitment start date

2016-02-19, 1394/11/30

##### Actual recruitment end date

2016-03-09, 1394/12/19

##### Trial completion date

empty

##### Scientific title

Study of the effect of resistance-aerobic training on cardiovascular index, quality of life, body composition and physical fitness in beta thalassemia major patients

##### Public title

Resistance-aerobic training in beta thalassemia major patients

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Have beta thalassemia major disease Have regular blood transfusion 19–25 years using of Desferal

### **Exclusion criteria:**

Absence for more than three exercise sessions Have acute heart disease Musculoskeletal abnormalities or any other medical condition that can contribute to exercise limitation

## **Age**

From **16 years** old to **40 years** old

## **Gender**

Both

## **Phase**

2-3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **40**

Actual sample size reached: **40**

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

Randomized

## **Randomization description**

Random assignment of samples to experimental and control groups- Lottery

## **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**

Ethics Committee of Islamic Azad University Rasht Branch

##### **Street address**

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

##### **City**

Rasht

##### **Province**

Guilan

##### **Postal code**

-

#### **Approval date**

2016-09-17, 1395/06/27

#### **Ethics committee reference number**

IR.IAU.RASHT.REC.1395.29

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Patient with beta thalassemia major

#### **ICD-10 code**

D56.1

#### **ICD-10 code description**

Beta thalassemia

## **Primary outcomes**

### 1

#### **Description**

Cardiovascular index

#### **Timepoint**

Before and 24 hours after the end of intervention

#### **Method of measurement**

Using by measuring heart rate, QTc distance, end systolic volume, end diastolic volume and ejection fraction

### 2

#### **Description**

Quality of life

#### **Timepoint**

Before and after the end of intervention

#### **Method of measurement**

Using by quality of life questionnaire (SF-36)

## **Secondary outcomes**

### 1

#### **Description**

Body composition

#### **Timepoint**

Before and after the end of intervention

#### **Method of measurement**

Using by measuring body mass index and fat percent

### 2

#### **Description**

Physical fitness

#### **Timepoint**

Before and after the end of intervention

#### **Method of measurement**

Using by measuring maximum oxygen consumption (VO<sub>2</sub>max) and muscle endurance

## **Intervention groups**

### 1

#### **Description**

Intervention group: doing six weeks, 2-3 time per week incremental resistance- aerobic training

#### **Category**

Other

## 2

### Description

Control group: no intervention will be conducted

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Amini Hospital

##### Full name of responsible person

Seyedeh Fatemeh Banihashemi Bazarzadeh

##### Street address

Shahid Amini Hospital, Imam Khomeini Street,  
Langarud, Guilan Province

##### City

Langarud

##### Province

Guilan

##### Postal code

-

##### Phone

+98 13 4252 4005

##### Email

shabani\_msn@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Ali Delpasand

##### Street address

Islamic Azad University Rasht Branch, Taleshan  
Bredge

##### City

Rasht

##### Province

Guilan

##### Postal code

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##### Phone

+98 13 3343 0503

##### Email

shabani\_msn@yahoo.com

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

personality, Researcher

##### Proportion provided by this source

100

##### Public or private sector

Private

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Seyedeh Fatemeh Banihashemi Bazarzadeh

##### Position

MA

##### Latest degree

Master

##### Other areas of specialty/work

Exercise physiology

##### Street address

Islamic Azad University Rasht Branch, Taleshan  
Bridge, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

-

##### Phone

+98 13 3343 0503

##### Email

shabani\_msn@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr Ramin Shabani

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Exercise physiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fatemeh Izaddoust

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

**Street address**

Islamic Azad University Rasht Branch, Taleshan

Bridge, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

-

**Phone**

## 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