

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 (VO₂max) 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,
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-

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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
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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

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Person responsible for scientific inquiries

Contact

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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

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Full name of responsible person

Fatemeh Izaddoust

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

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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