Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effects of cardiac rehabilitation exercises (aerobic and endurance exercises) on cardiac function, functional capacity, quality of life and mental health of patients with thalassemia major

Protocol summary

Study aim

Determining the effects of cardiac rehabilitation exercises (aerobic and endurance exercises) on cardiac function, functional capacity, quality of life and mental health of patients with thalassemia major.

Design

This research is a clinical trial type. Sampling is initially done based on the goal and based on the entry and exit criteria, and then 50 selected patients are divided into control and intervention groups by a simple random method after completing the informed consent form.

Settings and conduct

This study is conducted on patients with thalassemia major in Shahid Mohammadi Hospital in Bandar Abbas city. The study will be a single-blind study in two intervention and control groups, and the statistical analyst is unaware of the allocation of the study groups. In this study, outpatient cardiac rehabilitation is for 8 weeks (in the Cardiac Rehabilitation Clinic, Shahid Mohammadi Hospital). The two study groups will be followed up before and after the intervention and the main outcomes will be evaluated. The study is a single-blind study, in which the doctor and the patient are aware of the control and intervention groups, but the statistical analyst is blinded.

Participants/Inclusion and exclusion criteria

• Inclusion criteria: Thalassemia major patients who are undergoing regular blood transfusions and chelator therapy • Exclusion criteria: Severe exercise intolerance

Intervention groups

Patients in the intervention group do 8 weeks of planned rehabilitation exercises (including aerobic and resistance exercises)and patients in the control group are followed up every 2 weeks for 8 weeks by telephone in terms of clinical and therapeutic status.

Main outcome variables

Heart Rate Recovery, exercise capacity, quality of life and mental health, and the serum levels of ferritin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230515058202N1**
Registration date: **2024-01-24, 1402/11/04**
Registration timing: **retrospective**

Last update: **2024-01-24, 1402/11/04**
Update count: **0**

Registration date

2024-01-24, 1402/11/04

Registrant information

Name

yalda yousefi azari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 7000

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yaldayousefiazari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effects of cardiac rehabilitation exercises (aerobic and endurance exercises) on cardiac function, functional capacity, quality of life and mental health of patients with thalassemia major

Public title
Evaluating the effects of exercises in patients with thalassemia major

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Thalassemia major patients who undergo regular blood transfusions and receive packed cells every month. Patients receiving iron chelator with regular blood transfusion such as desferal or deferiprone at the same time. Left ventricular ejection fraction equal to or more than 50% New York Heart Association (NYHA) functional class I, II, or III. Being in the age range of 18 to 40 years Having the desire and motivation to participate in the training program
Exclusion criteria:
Severe exercise intolerance uncontrolled arrhythmia, uncontrolled angina pectoris, severe kidney or lung disease, musculoskeletal or neuromuscular conditions that preclude exercise or exercise testing, and signs or symptoms of ischemia and abnormal hemodynamic responses during previous incremental exercise test, suffering from severe mental and psychiatric diseases, use of psychoactive drugs, uncontrolled blood pressure and diabetes, clinical evidence of other secondary causes of pulmonary hypertension including HIV infection, hepatitis virus infection, Collagen vascular diseases, cirrhosis, chronic obstructive airway diseases and acquired heart disease associated with pulmonary hypertension.

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be done in the form of simple random allocation to equalize the sample size in the groups. Randomization will be done through tables of random or random numbers and by computers that set the numbers randomly. The table of random numbers that will be used was produced by the Institute of RAND (www.rand.org). These tables have random numbers in both rows and columns. First, the names of all patients are numbered. Then, in order to select the people of the intervention group from the table of random numbers, the researcher randomly chooses a number from the table and then moves in the direction of the row or column and chooses the next numbers in order until the last person of the intervention group is identified. Then the unselected people They are in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, blinding was done using a single-blind method, and the patients were randomly assigned to two intervention and control groups, and the clinical caregiver recorded the relevant information after the rehabilitation. The group provides this information to the analyst. The analyzer remains unaware of which group the information belongs to.

Placebo
Not used

Assignment
Parallel

Other design features
People are randomly divided into two groups. The first group receives rehabilitation intervention and the second group does not receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Bandar Abbas, the beginning of Imam Hossein Blvd., University of Medical
City
bandar abbas
Province
Hormozgan
Postal code
7919693116

Approval date
2023-08-23, 1402/06/01

Ethics committee reference number
IR.HUMS.REC.1402.271

Health conditions studied

1

Description of health condition studied
Thalassemia major disease

ICD-10 code
D56.1

ICD-10 code description
Beta thalassaemia

Primary outcomes

1

Description
ferritin
Timepoint
Before the intervention and after the intervention
Method of measurement
Serum ferritin level by chemiluminescence method with Abbott Architect i1000SR Immunoassay System

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before the intervention and after the intervention
Method of measurement
SF-36 questionnaire

2

Description
Mental health
Timepoint
Before the intervention and after the intervention
Method of measurement
SCL-90-R questionnaire

3

Description
HR Recovery
Timepoint
Before the intervention and after the intervention
Method of measurement
exercise test

4

Description
exercise capacity
Timepoint
Before the intervention and after the intervention
Method of measurement
6-minute walk test

5

Description
Cardiac function
Timepoint
Before the intervention and after the intervention
Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group: People in the intervention group do 8 weeks of planned rehabilitation exercises.The exercise program includes aerobic and resistance exercises. The aerobic exercise program consists of 1 hour of aerobic exercise, which consists of 10 minutes of warm-up (stretching of the upper and lower limbs), 20 to 30 minutes of exercise with a treadmill or cycle ergometer with an intensity of 70%. The maximum HR obtained from the exercise test is the cool-down (dynamic exercises with low intensity and stretching of the upper and lower limbs) and the resting phase (for 10 minutes). Aerobic exercise program is done twice a week for 8 weeks. In addition, in parallel and simultaneously, a resistance training protocol (twice a week, for 8 weeks, and on the days when the aerobic exercise program is not carried out) is implemented. Each session lasts for 1 hour and consists of warm-up periods, high-repetition/low-load resistance training program (HR/LL-RT) on the leg press and cool-down. The warm-up and cool-down sections also include body stretching. It is lower. Test subjects perform 3 sets in 2 minutes with a movement rhythm of 10 repetitions per minute and maintain the breathing rate. Each repetition takes 5 seconds (2 seconds of opening and 3 seconds of knee and hip flexion).) with a rhythm controlled by verbal commands. The sets are separated by 5-minute rest intervals. The exercise intensity is 30% of 1 RM. These patients are also under routine medical care and follow-up (i.e., regular visits by Cardiologist) are placed.
Category
Rehabilitation

2

Description
Control group: These patients are followed up every 2 weeks for 8 weeks by phone call. This call is to provide more information about adherence to the study protocol and to remind and encourage patients to continue with future visits and to ascertain whether there are any new changes in medical events. And whether or not there has been a drug since the previous contact, it takes place.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
shahid mohammadi hospital
Full name of responsible person
zahra saadat
Street address
Shahid Chamran Boulevard, Bandar Abbas, Hormozgan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bandare-abbas University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
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zahra saadat
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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Medical doctor
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General Practitioner
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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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available