Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of 12 weeks of submaximal aerobic training (swimming) on aerobic capacity and heart rate variability in girls with thalassemia major

Protocol summary

Study aim

Determining the effect of 12 weeks of submaximal aerobic training (swimming) on aerobic capacity and heart rate variability in girls with thalassemia major.

Design

The present study is a quasi-experimental study with parallel groups in which the allocation to intervention and control groups was non-randomized; the sample size included 30 girls with thalassemia major (10 in each group) and 15 healthy girls as the control group; this study was not blinded and did not have a trial phase because it is a non-randomized intervention study.

Settings and conduct

This study will be conducted to investigate the effect of exercise training on cardiovascular indices in patients with thalassemia major in Hamedan province. The method of implementation will include the evaluation of HRV indices and echocardiography before and after the exercise intervention. Due to the nature of the intervention (exercise in water), blinding was not performed in this study

Participants/Inclusion and exclusion criteria

The study includes girls aged 20 to 35 with a history of thalassemia major for more than 10 years, but those with neuropathy, cerebrovascular or ocular disorders, cardiorespiratory failure, high blood pressure, or taking medications that affect resting heart rate are excluded from the study

Intervention groups

The control group receives no intervention, the control group continues to take Desferal, and the experimental group participates in water aerobics in addition to Desferal.

Main outcome variables

Changes in HRV indices (time and frequency-based); Changes in structural and functional echocardiographic indices of the heart; Predictive model of the function of the cardiac autonomic system based on ECG and ECHO indices.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260209068813N1**
Registration date: **2026-02-28, 1404/12/09**
Registration timing: **retrospective**

Last update: **2026-02-28, 1404/12/09**
Update count: **0**

Registration date

2026-02-28, 1404/12/09

Registrant information

Name

Tayyebe Baghian

Name of organization / entity

The university of bu-ali sina

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-22, 1404/06/31

Expected recruitment end date

2025-12-20, 1404/09/29

Actual recruitment start date

2025-09-22, 1404/06/31

Actual recruitment end date

2025-12-05, 1404/09/14

Trial completion date

empty

Scientific title
The effect of 12 weeks of submaximal aerobic training (swimming) on aerobic capacity and heart rate variability in girls with thalassemia major

Public title
The effect of submaximal aerobic exercise on cardiac factors in patients with thalassemia major

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Women with thalassemia major Women with thalassemia major should have no history of heart disease

Exclusion criteria:
Patients are able to do exercise Non-smoking by the aforementioned patients Individuals with neuropathy, cerebrovascular or ocular disorders, cardiorespiratory failure, high blood pressure, or taking medications that affect resting heart rate were excluded from the study.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Our study is a quasi-experimental design with non-random group assignment, no possibility of blinding, using a control group for comparison, and with sampling limitations.In this study, for the first time, the simultaneous effect of submaximal aerobic exercise (swimming) on changes in heart rate and cardiac structure and function has been investigated

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

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Floor 5, Central Headquarters of the University of Medical Sciences, Shahid Fahmideh Blvd., Pohachouz Square, Hamedan

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Approval date
2025-01-19, 1403/10/30

Ethics committee reference number
IR.BASU.REC.1403.028

Health conditions studied

1

Description of health condition studied
Cardiac factors in thalassemia major patients

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Detailed changes in HRV indices (SDNN, RMSSD, 5SDANN, PNN50 HF, LF, (VLF, LF / HF) and echocardiographic indices (LV- AO- LA- RV- FS- EF- MPI- PWTS-PWTD- IVSTS- IVSTD) from the beginning of the study to the end of the intervention

Timepoint
HRV, echocardiography, and blood factors were measured in the pre-test, one week after the last blood transfusion, and in the post-test, 48 hours after the end of the training intervention.

Method of measurement
HRV was measured using a Holter monitoring device, and cardiac structure and function were measured using echocardiography.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Thalassemia major exercise (3 days a week for 12 weeks of submaximal aerobic exercise and water rehabilitation), exercise duration will range from 20 to 60 minutes, and the exercise will begin with an intensity of 40% of the heart rate and will gradually increase to 75% of the heart rate in the twelfth week (the intensity of the exercise will be proportional to the

patients' ability).

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Ekbatan Children's Hospital

Full name of responsible person
Dr. Maryam Nikofar

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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
The University of bu-ali Sina

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
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Full name of responsible person
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professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
I will preferably make a decision after carefully examining the aspects and consulting with other members of the research team
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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