Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of coenzyme Q10 supplement to decrease cardiac complications predictor factors in β-Thalassemia major patients

Protocol summary

Study aim

Determining the effect of coenzyme Q10 supplementation in reducing the level of cardiac complications predicting factors in patients with beta Thalassemia major referred to Hajar Hospital.

Design

The present semi-experimental study will be conducted on 50 thalassemia major patients. This study is a phase 3 clinical trial. This study is before and after and does not have a control group. In addition to the standard treatment (iron chelators such as deferoxamine, deferasirox, etc), the patients also receive a 100 mg co-enzyme Q10 tablet daily for eight weeks.

Settings and conduct

Fifty patients are chosen among the thalassemia patients referred to Shahrekord Hajar Hospital in 2023. These participants are chosen based on similarities (individuals with similar blood collection intervals). A before-and-after investigation will be carried out. There is no control group. Before intervention the following parameters proBNP, D-dimer, Troponin, EF, PAP, TRG, TAPSE, IVSD, LVDS, PW, AVPG, RVD, RVSM, LVDD, AO, LA, E, E' ,E wave ECG will be checked, and then, along with the standard treatment, they will be given a 100 mg co-enzyme Q10 tablet daily for eight weeks and the mentioned parameters are checked again.

Participants/Inclusion and exclusion criteria

Entry criteria: people with thalassemia major, non-entry criteria: occurrence of infection and inflammation and death of the patient, pregnancy or breastfeeding.

Intervention groups

The study will be a single group comparison before and after. The intervention group receives standard treatment + 100 mg Q10 tablets

Main outcome variables

Blood troponin level Blood ProBNP blood D-dimer level Echocardiography examination in terms of EF PAP TRG TAPSE IVSD LVDS PW AVPG RVD RVSM LVDD AO LA E E' E wave Electrocardiography examination in terms of Rhythm rate axis P wave PR interval QRS wave ST segment T wave QT interval

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056777N4**
Registration date: **2024-04-03, 1403/01/15**
Registration timing: **prospective**

Last update: **2024-04-03, 1403/01/15**
Update count: **0**

Registration date

2024-04-03, 1403/01/15

Registrant information

Name

Shima Rahmati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 5131

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-06, 1403/01/18

Expected recruitment end date

2024-10-09, 1403/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of coenzyme Q10 supplement to decrease cardiac complications predictor factors in β-Thalassemia major patients

Public title
Effect of coenzyme Q10 supplement to decrease cardiac complications in β-Thalassemia major patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Beta Thalassemia major Informed consent to participate in the intervention No history of underlying disease Not to use other supplements
Exclusion criteria:
Pregnancy or breastfeeding

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Science
Street address
Kashani street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435

Approval date
2023-11-27, 1402/09/06

Ethics committee reference number
IR.SKUMS.MED.REC.1402.060

Health conditions studied

1

Description of health condition studied
Beta Thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Blood quantitative Troponin level

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

2

Description
Blood N-terminal prohormone of brain natriuretic peptide (Nt-proBNP) level

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

3

Description
Blood D-dimer level

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

4

Description
Cardiac ejection fraction (EF)

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Echocardiography

5

Description

Pulmonary artery pressure (PAP)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

6

Description

Left ventricle end diastolic diameter (LVDD)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

7

Description

Left ventricle end systolic diameter (LVDS)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

8

Description

Pulsed wave (PW)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

9

Description

Interventricular septum thickness (IVSd)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

10

Description

Left atrium diameter (LA)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

11

Description

Aorta diameter (Ao)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

12

Description

Right ventricular dysfunction (RVD)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

13

Description

Right ventricular peak systolic myocardial velocity (RVSm)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

14

Description

Tricuspid Annular Plane Systolic Excursion (TAPSE)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

15

Description

Tricuspid regurgitation gradient (TRG)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

16

Description

Aortic valve pressure gradient (AVPG)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Echocardiography

17

Description

P wave characteristics

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Electrocardiography

18

Description
PR interval
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

19

Description
QRS wave characteristics
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

20

Description
ST segment characteristics
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

21

Description
QT interval
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

22

Description
T wave characteristics
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

23

Description
Heart Axis
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

24

Description
ECG Rhythm
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

25

Description
Heart Rate
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Electrocardiography

26

Description
Peak velocity of early diastolic transmitral flow (E)
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Echocardiography

27

Description
Peak velocity of early diastolic mitral annular motion (E')
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Echocardiography

28

Description
passive blood flow from the left atrium to the left ventricle (E wave)
Timepoint
Before the intervention and eight weeks after the intervention
Method of measurement
Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
50 individuals with major thalassemia will be selected. Laboratory parameters (Troponin, D-dimer, Nt-proBNP, EF, PAP) will be examined initially and recorded along

with demographic information in a checklist made by the researcher. Along with standard treatment (iron chelators such as deferoxamine, deferasirox, etc) they will also receive a daily dose of 100mg of Co-enzyme Q10 tablets (Golden Life) for eight weeks. After the eight weeks of medication, the parameters will be examined again.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Hajar hospital
Full name of responsible person
Nima Asgar dehkordi
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Parastar street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
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Kashani Street
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shimarahmati1987@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Nima Asgar dehkordi
Position
Intern
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
Street address
No. 7, 17th Ave., 17 shahrivar st.
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long
The access period will start 6 months after the results are published.

To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable
In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address nimanimanimana@gmail.com or the contact number 00989140868595.

What processes are involved for a request to access data/document
To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments