Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of coenzyme Q10 supplement on Prevention of hepatotoxicity Caused by iron-overload in patients with major β-thalassemia referred to Hajar Hospital

Protocol summary

Study aim

Determining the effect of co-enzyme Q10 supplementation on reducing liver damage caused by increased iron in patients with 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 ALT, AST, HB, Ferritin, ESR, CRP, TIBC, LDH 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

Inclusion criteria: People with thalassemia major
Exclusion criteria: viral hepatitis, use of hepatotoxic drugs

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

Level of blood AST Level of blood ALT Level of blood LDH Level of blood HB Level of blood ferritin Level of blood CRP Measuring ESR Measuring TIBC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056777N2**
Registration date: **2023-08-06, 1402/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-06, 1402/05/15**
Update count: **0**

Registration date

2023-08-06, 1402/05/15

Registrant information

Name

Shima Rahmati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 5131

Email address

rahmati.sh@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-02, 1401/12/11

Expected recruitment end date

2023-08-27, 1402/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of coenzyme Q10 supplement on Prevention of hepatotoxicity Caused by iron-overload in patients with major β-thalassemia referred to Hajar Hospital

Public title
The effect of coenzyme Q10 supplement on Prevention of hepatotoxicity in patients with major β-thalassemia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with thalassemia major Patients with thalassemia major with elevated liver enzymes Patients with thalassemia major with elevated inflammation markers

Exclusion criteria:
Patients with active viral hepatitis Hepatotoxic drugs consumption Hypersplenism

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 Sciences

Street address
Kashani street

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

Approval date
2022-10-04, 1401/07/12

Ethics committee reference number
IR.SKUMS.REC.1401.061

Health conditions studied

1

Description of health condition studied
Thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Level of aspartate aminotransferase (AST) in blood

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

2

Description
Level of alanine transaminase (ALT) in blood

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

3

Description
Level of hemoglobin (Hb) in blood

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

4

Description
Level of ferritin in blood

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Biochemical laboratory kit

5

Description
Measuring erythrocyte sedimentation rate (ESR)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Biochemical laboratory kit

6

Description

Level of C-reactive protein (Crp) in blood

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Biochemical laboratory kit

7

Description

Measuring Total iron binding capacity (TIBC)

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Biochemical laboratory kit

8

Description

Level of lactate dehydrogenase (LDH) in blood

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Biochemical laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

50 individuals with major thalassemia will be selected. Laboratory parameters (ALT, AST, HB, Ferritin, ESR, CRP, TIBC, LDH) 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

Milad Nami

Street address

Parastar street

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8816754633

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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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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

Milad Nami
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Kiavash Fekri
Position
Associate professor
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Subspecialist
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Person responsible for updating data

Contact
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Full name of responsible person
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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 miladnami75@gmail.com or the contact number 00989117640474
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