

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

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

## Public title

The effect of coenzyme Q10 supplement on Prevention of hepatotoxicity in patients with major  $\beta$ -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

**City**  
Shahrekord

**Province**  
Chahar-Mahal-va-Bakhtiari

**Postal code**  
8816754633

**Phone**  
+98 913 985 4865

**Email**  
miladnami75@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shahre-kord University of Medical Sciences

**Full name of responsible person**  
Elham Reisi

**Street address**  
Kashani Street

**City**  
Shahrekord

**Province**  
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**Phone**  
+98 38 3334 9507

**Email**  
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**

Milad Nami  
**Position**  
Student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Practitioner  
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Parastar  
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miladnami75@gmail.com

## 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  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Hematology  
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## Person responsible for updating data

### 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  
**Street address**

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**City**  
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**Province**  
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**Phone**  
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**Email**  
miladnami75@gmail.com

## 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