

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation the effect of co-enzyme Q10 supplementation on inhibition of ferroptosis in patients with thalassemia major referred to Shahrekord Hajer Hospital

#### Protocol summary

The level of ferritin, superoxide dismutase, glutathione peroxidase-4 GPX4, catalase, hemoglobin, ESR, CRP

#### Study aim

Determining the effect of coenzyme Q10 on inhibiting ferroptosis in patients with thalassemia major

#### Design

The present semi-experimental study is a before and after clinical trial without control group done on 50 patients with thalassemia major. In addition to the standard treatment, the patients also receive a 100 mg Q10 tablet daily for eight weeks. Before the study, the parameters of ferroptosis including superoxide dismutase (SOD), catalase, glutathione peroxidase, ferritin, hemoglobin, ESR and CRP will be evaluated, and after eight weeks of intervention, the parameters will be evaluated again.

#### Settings and conduct

50 patients are selected from the thalassemia patients referred to Hajer Shahrekord Hospital in 1402. These patients are selected in a similar way (patients who are similar in terms of blood collection intervals). this study is a before and after clinical trial without control group. The relevant laboratory parameters including superoxide dismutase (SOD), catalase, glutathione peroxidase, ferritin, hemoglobin, ESR and CRP will be measured for these patients before start intervention (baseline), and then, after eight weeks of taking one 100 mg Q10 tablet daily, in addition to the standard treatment, Patients will also receive the supplement

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: patient with thalassemia major  
Exit criteria: Patient non-cooperation  
The presence of side effects  
People who suffer from infection and inflammation.  
death of the patient

#### 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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221211056777N1**

Registration date: **2023-01-22, 1401/11/02**

Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**

Update count: **0**

##### Registration date

2023-01-22, 1401/11/02

##### 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**  
Evaluation the effect of co-enzyme Q10 supplementation on inhibition of ferroptosis in patients with thalassemia major referred to Shahrekord Hajer Hospital

**Public title**  
Evaluation the effect of co-enzyme Q10 in patients with thalassemia major

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
patient with thalassemia major  
**Exclusion criteria:**  
Non-cooperation of the patient The presence of side effects People who suffer from infection and inflammation. Death of the patient

**Age**  
No age limit

**Gender**  
Both

**Phase**  
1

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: 50

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The data analyst does not know whether the collected data are related to before or after the intervention

**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.1401.116

## Health conditions studied

1

**Description of health condition studied**  
thalassemia major  
**ICD-10 code**  
D56.1  
**ICD-10 code description**  
Beta thalassemia

## Primary outcomes

1

**Description**  
The level of superoxide dismutase, catalase and peroxidase enzymes and ferritin serum level. ESR, CRP

**Timepoint**  
Before the intervention and eight weeks after the intervention

**Method of measurement**  
ELISA test kit

## Secondary outcomes

empty

## Intervention groups

1

**Description**  
50 patients with thalassemia major are selected. The laboratory parameters (superoxide dismutase (SOD), catalase and glutathione peroxidase, ferritin, hemoglobin, ESR and CRP) will be checked by ELISA method for these patients before start intervention (baseline), and then, after eight weeks of taking one 100 mg Q10 tablet (Golden Life Company) daily.

**Category**  
Treatment - Drugs

## Recruitment centers

1

**Recruitment center**  
**Name of recruitment center**  
Shahrekord Hajar hospital  
**Full name of responsible person**

Shima Rahmati  
**Street address**  
Parastar street  
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8816754633  
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shimarahmati1987@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  
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**Email**  
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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**  
Shima Rahmati  
**Position**

Researcher. Cancer Research Center  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Biotechnology  
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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  
**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**  
Shima Rahmati  
**Position**  
Research Assistant in Cancer Research Center  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Biotechnology  
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**City**  
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shimarahmati1987@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 shimarahmati1987@gmail.com or the contact number 00989139854865

**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**