

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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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

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Person responsible for updating data

Contact

Name of organization / entity
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Research Assistant in Cancer Research Center
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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 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