# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effect of Q10 on laboratory findings in thalassemia patients treated with Iron chelators: a double-blind clinical trial

## Protocol summary

**Study aim**

The aim of the present study is to investigate the effect of Q10 on laboratory findings in thalassemia patients treated with Iron chelators.

**Design**

This study is a double-blind parallel clinical trial with a 3-month intervention period, in which people are divided into two groups of 43 people randomly using Randomized Allocation Software.

**Settings and conduct**

This study will be conducted at Shahid Mohammadi Hospital and Aburihan Bandar Abbas Center affiliated with Hormozgan University of Medical Sciences. After explaining the study to the patient and obtaining informed consent, the patients are placed in one group and the treatment begins. At the beginning and at the end of the study (3 months later), 10 cc of blood and urine tests were also performed to check the effectiveness of the treatment. In this study, blinding will be done for participants, personnel, and researchers. In this way, drugs and placebo will be placed in the same packages by a person outside the study.

**Participants/Inclusion and exclusion criteria**

Patients with major and intermedia beta-thalassemia disease; patients who have had a history of taking Iron chelators regularly in the past three months, if they wish to cooperate (consent form will be completed by the parents of the patients for children under 18 years old and the patients themselves for patients over 18 years old).

**Intervention groups**

Group 1) 100 mg of ketones will be given daily for 3 months to thalassemia patients treated with Iron chelators. Group 2) Placebo pill (100mg) which does not contain an interfering agent, was given daily for 3 months to thalassemia patients treated with Iron chelators will be given.

**Main outcome variables**

Determining the effectiveness of intervention after treatment using laboratory parameters (urea, creatinine, GFR, uric acid, pr/cr ratio) Using a biochemistry autoanalyzer device

## General information

**Reason for update**

Due to the fact that most thalassemia patients take several drugs at the same time, we decided to investigate different drugs so that more people are included in the study and different patients are investigated.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20221102056386N1**
Registration date: **2023-03-03, 1401/12/12**
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **2**

**Registration date**

2023-03-03, 1401/12/12

**Registrant information**

**Name**
Narjes Seddighi
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-04-08, 1402/01/19

**Expected recruitment end date**
2024-03-09, 1402/12/19
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of Q10 on laboratory findings in thalassemia patients treated with Iron chelators: a double-blind clinical trial

**Public title**
Investigating the effect of Q10 in thalassemia patients treated with Iron chelators
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with major and intermedia beta thalassemia disease History of taking Iron chelators regularly in the last three months Age between 2 and 65 years
**Exclusion criteria:**
Having an active infection Existence of contraindications to the studied drugs
**Age**
From **2 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **86**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Before starting the study, all participants will be explained that they will be divided into two intervention (A) and control (B) groups. In this trial, we had two groups of 4 blocks (including 2 participants in drug group A and 2 participants in placebo group B). Production tools are also used from random sequence generation software (random allocation software) that this sequence generation software gives items that are able to generate a random sequences by block building method on simple structures. Blocked randomization is for the purpose of making sure that precisely equal number of participants are included in the intervention and control group at consecutive but equal time intervals. The randomization process is done by methodology consultant and the clinical researchers are not aware of the randomization method. Concealment Allocation refers to the method used to perform a random sequence on participants in the study, in such a way that the allocated group is not known before the allocation of the individual. By using opaque and sealed envelopes with a random sequence (Sequentially numbered, seal, opaque envelopes), in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order They are placed. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, blinding will be done for participants and researchers. In this way, the medicine and placebo will be placed in the same packages by a person outside the study, which will be labeled with A and B codes. The given codes will be provided to researchers after statistical analysis and when writing the article. To blind the participants and reduce their bias, it was explained to them only at the beginning of the study that they will receive one of two types of intervention and they will not be told the exact type of supplement.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Hormozgan University of Medical Sciences
**Street address**
Imam Hossein Blvd., Hormozgan University of Medical Sciences Campus, Research and Technology Vice-Chancellor Building
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**Province**
Hormozgan
**Postal code**
7919693116
**Approval date**
2022-12-18, 1401/09/27
**Ethics committee reference number**
IR.HUMS.REC.1401.309

## Health conditions studied

### 1

**Description of health condition studied**
Thalassemia
**ICD-10 code**
D56

**ICD-10 code description**
Thalassemia

## Primary outcomes

### 1

**Description**
Glomerular filtration rate
**Timepoint**
At the beginning and end of the third month of using Q10
**Method of measurement**
Autoanalyzer device

### 2

**Description**
Blood Urea Nitrogen
**Timepoint**
At the beginning and end of the third month of using Q10
**Method of measurement**
Autoanalyzer device

### 3

**Description**
Creatinine
**Timepoint**
At the beginning and end of the third month of using Q10
**Method of measurement**
Autoanalyzer device

### 4

**Description**
Uric acid
**Timepoint**
At the beginning and end of the third month of using Q10
**Method of measurement**
Autoanalyzer device

### 5

**Description**
Pr/Cr ratio
**Timepoint**
At the beginning and end of the third month of using Q10
**Method of measurement**
Autoanalyzer device

## Secondary outcomes

### 1

**Description**
Side effects of the studied drugs, especially those such as hypersensitivity reactions, allergies, shock, anemia, hypotension, nausea and vomiting, diarrhea, gastrointestinal spasms, weakness and lethargy, headache, and rash.
**Timepoint**
Side effects are recorded daily in the studied groups.
**Method of measurement**
Examining patients' files and using checklists

### 2

**Description**
Improvement of biochemical parameters of patients (Complete blood count tests, ferritin, C-reactive protein, aspartate aminotransferase, alanine transaminase, uric acid, lipid profile, albumin, fasting blood sugar)
**Timepoint**
Beginning of study and end of study
**Method of measurement**
Use of cell counter and autoanalyzer device

## Intervention groups

### 1

**Description**
Intervention group: Receiving 100 mg of Q10 tablets (Provided by Shari Pharmaceutical Company) daily for 3 months to thalassemia patients treated with Iron chelators
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Includes patients who receive 100 mg of placebo daily, which does not contain any type of intervention agent, for three months
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
The Great Prophet Research and Educational Complex Research Center
**Full name of responsible person**
Dr Parvin Kamkar
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## Sponsors / Funding sources

**1**

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**Full name of responsible person**
Vali alipoor
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research@hums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Bandare-abbas 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

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available