# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluation the Effect of Silymarin on Inflammatory Markers in Comparison with Placebo in β-thalassemia Patients undergoing Iron Chelation Therapy

## Protocol summary


**Summary**

A randomized, double-blind and crossover trial was performed on 70 beta thalassemia patients at the Thalassemia Research Center in Mazandaran University of Medical Sciences. The aim of this study was to determine of silymarin effects on serum inflammatory indexes in comparison with placebo in β-thalassemia patients undergoing iron chelation therapy. This study had been designed in three phases. During the first phase, patients were received silymarin tablet (420 mg - three times a day) or placebo tablet (three times a day) for 12-weeks. Phase 2 was a washout phase during 2-weeks. During phase 3, patients who randomly were assigned to receive silymarin were changed to receive placebo. Also, patients randomly were assigned to receive placebo during phase 1 were changed to receive silymarin. Plasma CRP, interleukin-6 and interleukin-10 level were measured immediately before and after each period.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015101411819N3**
Registration date: **2015-12-07, 1394/09/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-12-07, 1394/09/16

**Registrant information**


**Name**

Hadi Darvishi Khezri

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice chancellor for research, Mazandaran University of Medical Sciences


**Expected recruitment start date**

2014-12-22, 1393/10/01

**Expected recruitment end date**

2015-06-22, 1394/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation the Effect of Silymarin on Inflammatory Markers in Comparison with Placebo in β-thalassemia Patients undergoing Iron Chelation Therapy

**Public title**

Effect of Silymarin on Inflammatory Markers in β-thalassemia Patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients with beta thalassemia major; History of iron chelation therapy for at least 2 years; Having relatively constant average dose of iron chelation during 3 months ago; Ferritin up to 1000 µg/L Exclusion

criteria: Change therapeutic regimen with iron chelation during the study (6 months)

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

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

**Blinding description**

**Placebo**
Used

**Assignment**
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Mazandaran University of Medical Sciences

**Street address**
7 km of sea road, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran.

**City**
Sari

**Postal code**

**Approval date**
2014-10-23, 1393/08/01

**Ethics committee reference number**
1126

## Health conditions studied

### 1

**Description of health condition studied**
Thalassaemia

**ICD-10 code**
D56.1

**ICD-10 code description**
Beta thalassaemia

## Primary outcomes

### 1

**Description**
Serum malondialdehyde, carbonyl protein and total anti-oxidant of serum level

**Timepoint**
1-Before the first phase 2- After the washout period (after 2 weeks of the end of the first phase) 3- After the third phase (after 26 weeks)

**Method of measurement**
Before the first phase - After the washout period -After the third phase

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Patients in the intervention group received 420 milligrams of silymarin tablets, three times per day for 3 months.

**Category**
Treatment - Drugs

### 2

**Description**
Patients in the control group received placebo tablets, three times per day for 3 months.

**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Thalassemia Research Center

**Full name of responsible person**
Hadi Darvishi Khezri

**Street address**
Thalassemia Research Center, Bu-Ali Hospital, Sari, Mazandaran, Iran

**City**
Sari

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Vice chancellor for research, Mazandaran University of Medical Sciences

**Full name of responsible person**
Ahmad Ali Enayati

**Street address**

Moallem Square, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

**City**
Sari

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Vice chancellor for research, Mazandaran University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
*empty*

**Domestic or foreign origin**
*empty*

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Hadi Darvishi Khezri

**Position**
Student in PhD by research

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
Ebrahim Salehifar

**Position**
Professor of clinical pharmacology

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**
Student in PhD by research

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*

**Study Protocol**
*empty*

**Statistical Analysis Plan**
*empty*

**Informed Consent Form**
*empty*

**Clinical Study Report**
*empty*

**Analytic Code**
*empty*

**Data Dictionary**
*empty*