

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the Effect of Silymarin on Oxidative Stress Markers in Comparison with Placebo in $\beta$ -thalassemia Patients undergoing Iron

#### 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 determination of silymarin effects on serum inflammatory indexes in comparison with placebo in  $\beta$ -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. Serum malondialdehyde, carbonyl protein and total anti-oxidant were measured before and after both periods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015101411819N4**

Registration date: **2015-12-21, 1394/09/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-21, 1394/09/30

##### Registrant information

##### Name

Hadi Darvishi Khezri

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1213 3857

##### Email address

hadidarvishi@iausari.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Moallem Square, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

##### 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 Oxidative Stress Markers in Comparison with Placebo in  $\beta$ -thalassemia Patients undergoing Iron

##### Public title

Effect of Silymarin on Oxidative Stress Status in  $\beta$ -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  $\mu$ g/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

N/A

## 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

Thalassemia

#### ICD-10 code

D56.1

#### ICD-10 code description

Beta thalassaemia

## Primary outcomes

### 1

#### Description

Serum malondialdehyde

## 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

### 2

#### Description

Serum carbonyl protein

#### 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

### 3

#### Description

Serum antioxidant

#### 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

### 1

#### Description

Incidence of adverse drug reactions

#### 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

## Intervention groups

### 1

#### Description

Patients in the intervention group received 420 milligrams of silymarin tablets, three times per day.

#### Category

Treatment - Drugs

### 2

#### Description

Patients in the control group received placebo tablets, three times per day.

#### 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati

**Street address**

Vice chancellor for research, 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**

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**

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**Position**

Professor of clinical pharmacology

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

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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*