

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the Effect of Silymarin on Serum Ferritin and Iron Level 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 determination of silymarin effects on serum ferritin and iron levels 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. Serum iron, ferritin, and TIBC were measured immediately before and after each period. Change of treatment regimen was exclusion criteria during study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101211819N2**

Registration date: **2016-04-10, 1395/01/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-10, 1395/01/22

Registrant information

Name

Hadi Darvishi Khezri

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

7 km of sea road, 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 Serum Ferritin and Iron Level in Comparison with Placebo in β -thalassemia Patients undergoing Iron Chelation Therapy

Public title

Effect of Silymarin on Serum Ferritin and Iron Level 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 μ 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

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)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

Street address

Vice chancellor for research, Moallem Square, 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 Iron 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

Serum Iron was measured by spectrophotometry

2

Description

Serum Ferritin 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

Serum ferritin was measured by ELISA test

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

Data collection form

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, Bu-Ali Hospital, Sari,

Mazandaran, Iran

Full name of responsible person

Hadi Darvishi Khezri

Street address

Thalassemia Research Center, Bu-Ali Hospital, Sari,
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City

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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

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

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

7 km of sea road, Mazandaran University of Medical
Sciences, Sari, Mazandaran, Iran

Full name of responsible person

Hadi Darvishi Khezri

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