Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

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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 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)
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, 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

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

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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

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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