Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the Effect of Silymarin on Oxidative Stress Markers in Comparison with Placebo in β-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 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 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

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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 β-thalassemia Patients undergoing Iron

Public title

Effect of Silymarin on Oxidative Stress Status 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
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

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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
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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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