Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Combined therapy of silymarin and desferrioxamine in patients with b-thalassemia major: a randomized double-blind clinical trial

Protocol summary

Summary
Silymarin, a flavonolignan complex isolated from Silybum marianum, has a strong antioxidant, hepatoprotective and iron chelating activities. The present study has been designed to investigate the therapeutic activity of orally administered silymarin in patients with thalassemia major under conventional iron chelation therapy. A 6-month randomized, double-blind, clinical trial was conducted in 140 beta-thalassemia major patients in two well-matched groups. Patients are randomized to receive a silymarin tablet (140 mg) three times a day plus conventional desferrioxamine therapy or the same therapy but a placebo tablet instead of silymarin. Clinical laboratory tests of iron status and liver function are assessed at the beginning and the end of the trial.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT138804022067N1**
Registration date: **2009-10-02, 1388/07/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2009-10-02, 1388/07/10

Registrant information

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Marjan Gharagozloo
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Isfahan University of Medical Sciences, Isfahan, Iran, and

Expected recruitment start date
2009-05-12, 1388/02/22
Expected recruitment end date
2009-08-30, 1388/06/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Combined therapy of silymarin and desferrioxamine in patients with b-thalassemia major: a randomized double-blind clinical trial

Public title
Therapeutic effect of silymarin in beta-thalassemia major
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Presence of major Beta-thalassemia, age 12 years or older, iron overload condition (with serum ferritin levels between 1000-5000 ng/mL) during 6 months prior to study, regular deferoxamine administration (50 mg/kg), receiving continuous blood transfusions maintained at a hemoglobin level of 9.5 g/dl, negative CRP test at the beginning of the study
Exclusion criteria: Presence of hepatitis B or C infection, positive HIV test, gastrointestinal problemss preventing absorption of an oral medication presence of chronic renal or heart failure, iron chelating therapy with iron chelators other than desferrioxamine, pregnancy
Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar jerib street, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2008-12-22, 1387/10/02

Ethics committee reference number

187050

Health conditions studied

1

Description of health condition studied

Beta-Thalassemia major

ICD-10 code

D56.1

ICD-10 code description

Beta-Thalassemia major

Primary outcomes

1

Description

Serum ferritin

Timepoint

3 months and 6 months from beginning of the trial

Method of measurement

ELISA assay

2

Description

Liver enzymes (SGOT, SGPT, Alkaline Phosphatase)

Timepoint

3 months and 6 months from beginning of the trial

Method of measurement

ELISA assay

Secondary outcomes

empty

Intervention groups

1

Description

Silymarin Capsule, 140 mg, 3 times a day + desferal 50 mg/kg

Category

Treatment - Drugs

2

Description

Placebo capsules Similar to Silymarin + desferal injection 50 mg/kg

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al Shohada hospital, Thalassemia devision, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Hamid Hourfar

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi,

Street address

Vice-chancellery of Research Affairs, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

ROTTAPHARM | MADAUS

Full name of responsible person

Dr. Horst-Ulrich Tuellner

Street address

Madaus GmbH, Colonia Allee 15, 51067 Köln

City

Köln

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ROTTAPHARM | MADAUS

Proportion provided by this source

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Immunology, Isfahan Medical School

Full name of responsible person

Dr. Marjan Gharagozloo

Position

Assistant professor, PhD

Other areas of specialty/work

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Name of organization / entity

Department of Immunology, School of Medicine

Full name of responsible person

Nafiseh Esmaeil

Position

MSc

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