# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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**

**Name**
Marjan Gharagozloo
**Name of organization / entity**
Isfahan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 79 22428
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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**

**Street address**

Medical School, Isfahan University of Medical Sciences

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## Person responsible for updating data

**Contact**

**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*