

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparative study of intravenous and subcutaneous high-dose desferal on Iron overload in thalassemia major patient with decrease in Ejection-Fraction.

Protocol summary

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Summary

After inclusion and exclusion criteria implementation, patients will be selected. After the consent taking, ferritin levels will be measured and recorded. Patients will be divided in 2 groups randomly. In first group (case) intravenous and in second group (control) subcutaneous desferal administration will be performed for a week, 200 mg/kg/day. After the treatment period, serum ferritin levels will be measured again and a week later, echocardiography was also performed. All data will be recorded and then analyzed. After final analysis, the results will be announced.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206289827N2**
Registration date: **2012-07-14, 1391/04/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-14, 1391/04/24

Registrant information

Name

Afshin Safari

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 83 1836 7398

Email address

Recruitment status

Recruitment complete

Funding source

Research Council of Kermanshah University of Medical Sciences and Health Services.

Expected recruitment start date

2011-11-21, 1390/08/30

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of intravenous and subcutaneous high-dose desferal on Iron overload in thalassemia major patient with decrease in Ejection-Fraction.

Public title

Comparison of two methods of administration of deferoxamine (intravenous and subcutaneous) in terms of impact on reducing iron overload in thalassemia patients who have suffered heart failure.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: suffering major Thalassemia and cardiac ejection fraction less than 50%. Exclusion criteria: inflammatory disease; anemia and liver disorders.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences and Health Services

Street address

Research Council of Kermanshah University of Medical Sciences and Health Services, No2 Building, Shahid-Beheshti Blvd, Kermanshah.

City

Kermanshah

Postal code

6714858773

Approval date

2011-10-23, 1390/08/01

Ethics committee reference number

7730

Health conditions studied

1

Description of health condition studied

Iron overload.

ICD-10 code

R79.0

ICD-10 code description

Abnormal level of blood mineral.

Primary outcomes

1

Description

Serum ferritin

Timepoint

1 week after intervention (desferal administration)

Method of measurement

Use of ELISA method, unit will be mg/L

Secondary outcomes

1

Description

Cardiac Ejection Fraction.

Timepoint

2 weeks after intervention.

Method of measurement

Using Ecocardiography, the unit will be "percent"

Intervention groups

1

Description

Case Group: Desferal (Desferrioxamine Mesylate 500mg) intravenous administration will be performed for a week, 200 mg/kg/day.

Category

Treatment - Drugs

2

Description

Control group:Desferal (Desferrioxamine Mesylate 500mg) subcutaneous administration will be performed for a week, 200 mg/kg/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Thalassemia Center of Dr Mohamad Kermanshahi Hospital.

Full name of responsible person

Khosro Karimi

Street address

Dr Mohamad Kermanshahi Hospital, Rafatie St, Kermanshah.

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Research Council of Kermanshah University of
Medical Sciences and Health Services, No2 Building,
Shahid-Beheshti Blvd, Kermanshah.

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences and Health
Services

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**

Kermanshah University of Medical Sciences and
Health Services

Full name of responsible person

Khosro Karimi

Position

Intern (Medical student)

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences and
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Full name of responsible person

Dr. Mohamadreza Golpaygani

Position

Hematology and Oncology Subspecialist

Other areas of specialty/work**Street address**

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Fax**Email**

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Web page address**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