Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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 Sevices

Country

Iran (Islamic Republic of)

Phone

+98 83 1836 7398

Email address

mehramini143@kums.ac.ir

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

Pediatrics Department of Imam-Reza Hospital, Sorkhelijhe, Kermanshah.

City

Kermabshah

Postal code

6714858773

Phone

+98 83 1427 6302

Fax

+98 83 1427 6316

Email

mehramini143@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Mohamadreza Golpaygani

Position

Hematology and Oncology Subspecialist

Other areas of specialty/work

Street address

Pediatrics Department of Imam-Reza Hospital, Sorkhelijhe, Kermanshah.

City

Kermanshah

Postal code

6714758773

Phone

+98 83 1427 6302

Fax

+98 83 1427 6316

Email

mehramini143@kums.ac.ir

Web page address

Person responsible for updating data

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

Pediatrics Department of Imam-Reza Hospital, Sorkhelijhe, Kermanshah.

City

Kermanshah

Postal code

6714858773

Phone

+98 83 1427 6302

Fax

Email

mehramini143@kums.ac.ir

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