Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of Deferazirox and Deferoxamine on Serum Ferritin Levels Changes in Major Beta Thalassemia Patients

Protocol summary

Study aim
Comparison of deferasirox and deferoxamine on serum ferritin level changes in beta thalassemia major patients
Design
Clinical trial, parallel groups, unblinded, randomized, 41 patients
Settings and conduct
The first group was treated with deferasirox (Nanojid) ± Defriprone (L1) and the second group was treated with defroxamine (Desferal) ± Defriprone (L1). All patients received the drugs at a dose of 14 mg/kg and required blood tests including monthly CBC, ferritin and creatinine were checked for patients every three months. Finally, all statistical analysis was performed using software SPSS21.
Participants/Inclusion and exclusion criteria
The age of the patients was 2 years and older No gender restrictions Normal serum creatinine levels Absence of proteinuria in U/A patients
Intervention groups
The first group was treated with deferasirox (Nanojade) ± Deferiprone(L1) and the second group was treated with deferoxamine (Desferal) ± Deferiprone(L1).
Main outcome variables
serum ferritin level changes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190817044550N4**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **retrospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**
Registration date
2023-06-18, 1402/03/28

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-23, 1401/08/01
Expected recruitment end date
2023-05-22, 1402/03/01
Actual recruitment start date
2022-10-23, 1401/08/01
Actual recruitment end date
2023-05-22, 1402/03/01
Trial completion date
2023-05-22, 1402/03/01

Scientific title
Comparison of Deferazirox and Deferoxamine on Serum Ferritin Levels Changes in Major Beta Thalassemia Patients

Public title
Comparison of Deferazirox and Deferoxamine on Serum Ferritin Levels Changes in Major Beta Thalassemia Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age of the patients was 2 years and older Have a

normal serum creatinine level Absence of proteinuria in U/A patients The serum ferritin levels of the patients should be above 1000 mg/dl, or the patients should have had more than 10 blood transfusions, or the volume of blood transferred should be more than 100 cc/kg
Exclusion criteria:
Pregnancy and breastfeeding Resistant levels greater than 5 times the normal value of liver transaminase Severe nausea and vomiting in the patient Patient refusal to participate in the study

Age
From **2 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Actual sample size reached: **41**
Randomization (investigator's opinion)
Randomized
Randomization description
We used the permuted block randomization method, and these blocks were randomly designed in Excel software, and then groups equal to the allocation of a as the intervention group and b as the control group were performed.
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
Ethics Committee of Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, Ghaffari Street
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South Khorasan
Postal code
9717853577
Approval date
2022-10-10, 1401/07/18
Ethics committee reference number
IR.BUMS.REC.1401.263

Health conditions studied

1

Description of health condition studied
beta thalassemia major
ICD-10 code
D56.1
ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Serum ferritin level
Timepoint
Measurement of serum ferritin level at the beginning of the study (before the start of the intervention), 3 and 6 months after the start of the intervention
Method of measurement
Biochemical test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treated with deferasirox (Nanojade) ± Deferiprone
Category
Treatment - Drugs

2

Description
Intervention group: Treated with deferoxamine (Desferal) ± deferiprone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The data obtained from this project will eventually be reported as standard and general, and reporting personal information by individuals does not seem necessary.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Demographic information and information about the main outcome of this project can be shared.
When the data will become available and for how long
Start of access period 1 year after printing the results
To whom data/document is available
The data of this project can be shared by all aspiring researchers working in academic and scientific institutes.
Under which criteria data/document could be used
Appropriate scientific use of the data of this study in order to improve the quality of similar studies is unimpeded.
From where data/document is obtainable
The data of the present research is possible by announcing the request via email khorashadi4590@gmail.com and also na_chahkandi@yahoo.com.
What processes are involved for a request to access data/document
After confirming the eligibility of the person requesting the information, the data will be sent as soon as possible via the above emails.
Comments