Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparsion of combination therapy with Deferiprone plus desferrioxamine versus desferrioxamine alone in patients with major beta thalassemia

Protocol summary

Summary

Iron overload especially in the heart is one of the most important causes of death among patients with major thalassemia. Iron uptake by using iron chelators is one of the main therapeutic methods in the patients. This study was done to compare the therapeutic effects of defroxamine and deferiprone combination therapy and defroxamine alone in patients of Mazandaran Iran. In this clinical trial, major thalassemia patients with serum ferritin > 3000 ng/ml were divided in two groups and matched based on age, sex, serum ferritin level and systolic cardiac function (LVEF). First group received desferrixamine (DFO) alone 50-60 mg/kg/dAY, and second received combination therapy of deferiprone 50-75mg/kg/DAY and DFO 30-35 mg/kg/DAY. Patients were visited every 6 months for physical exam and serum ferritin, mean of Hb, AST, ALT and LVEF recorded from 6 months before the study and then measured and recorded in each visit. Data were analyzed using repeated measurements, t-test and χ^2 test .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810203032N1**
Registration date: **2010-11-08, 1389/08/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-08, 1389/08/17

Registrant information

Name

Hossein Karami

Name of organization / entity

Mazandaran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1223 4506

Email address

hokarami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Mazandran University of Medical Sciences

Expected recruitment start date

2005-12-22, 1384/10/01

Expected recruitment end date

2007-12-22, 1386/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of combination therapy with Deferiprone plus desferrioxamine versus desferrioxamine alone in patients with major beta thalassemia

Public title

Treatment effect of deferiprone and desferrioxamine in beta thalassemia major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Confirmed major thalassemia by Hemoglubin elctrophoresis 2- Age ranged 5-30 years 3- Serum ferritin level more than 3000 ng/ml 4- Written

consent from patients or parents Exclusion criteria: 1- Disagreement of patients or parents for begining of treatment 2- Deferiprone sensitivity 3- Desferrioxamine sensitivity 3-

Age
From **5 years** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not 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
Mazandaran University of Medical sciences, Sari/ Iran
Street address
Mazandaran University of Medical sciences, Sari/ Iran
City
Sari
Postal code
Approval date
empty
Ethics committee reference number
8412

Health conditions studied

1

Description of health condition studied
Major Thalassemia
ICD-10 code
D56.1
ICD-10 code description
Beta thalassaemia

Primary outcomes

1

Description
Serum ferritin
Timepoint
6 months
Method of measurement
Immuno Radiaometric Assay

2

Description
Left ventricle ejection fraction
Timepoint
6 months
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Hemoglobin
Timepoint
6 months
Method of measurement
Electronic counter

2

Description
AST
Timepoint
6 months
Method of measurement
PARS AZMUN Kit

3

Description
ALT
Timepoint
6 months
Method of measurement
PARS AZMUN Kit

Intervention groups

1

Description
Desferrixamine alone 50-60 mg/kg/day
Category
Treatment - Drugs

2

Description
Combination therapy of deferiprone 50-75 mg/kg/day and desferrioxamine 30-35 mg/kg/day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran thalassemia research center
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazndaran University of Medical Science
Full name of responsible person
Hossein Karami
Street address
Mazndaran University of Medical Science
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazndaran University of Medical Science
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
Mazndaran University of Medical Science
Full name of responsible person
Hossein Karami
Position
Assistant Professor of Pediatric Hematology and Oncology
Other areas of specialty/work
Street address
Mazandaran thalassemia research center, Booali Sina Hospital, Sari
City
Sari
Postal code
4815733971
Phone
+98 15 1214 4295
Fax
Email
hokarami@mazums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazndaran University of Medical Sciences
Full name of responsible person
Hossein Karami
Position
Assistant Professor of Pediatric Hematology and Oncology
Other areas of specialty/work
Street address
Mazandaran thalassemia research center, Booali Sina Hospital, Sari
City
Sari
Postal code
4815733971
Phone
+98 15 1214 4295
Fax
Email
hokarami@mazums.ac.ir
Web page address

Person responsible for updating data

Contact

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