

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparision 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 deferoxamine and deferiprone combination therapy and deferoxamine 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 desferrioxamine (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

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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

Comparision 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 Hemoglobin 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 beginning 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 Radioaometric 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

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Name of organization / entity

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Full name of responsible person

Hossein Karami

Position

Assistant Professor of Pediatric Hematology and Oncology

Other areas of specialty/work

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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