Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Oral versus Injectable Iron Chelation Therapy in Reducing Serum Ferritin Levels in Patients with Transfusion Dependent Thalassemia

Protocol summary

Study aim

To compare the mean serum ferritin level with oral versus injectable iron chelation therapy in patients with transfusion dependent thalassemia.

Design

A single center, open-labelled, randomized controlled trial. Children in the intervension group will be given oral iron chelation therapy i.e. daily Deferiprone at a dose of 75mg/kg/day in two to three divided doses for a period of 6-months. In the control group, children will be given injectable iron chelation therapy i.e. single dose of deferoxamine 4 mmol, 6 days a week for a duration of 6-months). Sample size will be 50 children (25 in each gropu) as per inclusion and exclusion criteria.

Settings and conduct

This open labelled trial will be conducted at The Department of Pediatric Medicine, DHQ Teaching Hospital, Dera Ghazi Khan, Pakistan

Participants/Inclusion and exclusion criteria

Inclusion criteria will be children of both genders and age >1 up to 15 years presenting with beta thalassemia major. Exclusion criteria will be children already taking trial treatment, or liver failure (ALT & AST >50IU), anemia (hemoglobin level <10 g/dl) or those who will lose during the follow ups.

Intervention groups

In the intervension group will be given oral iron chelation therapy i.e. daily Deferiprone at a dose of 75mg/kg/day in two to three divided doses for a period of 6-months. Control group: Children will be given injectable iron chelation therapy i.e. single dose of deferoxamine 4 mmol (225 mg) daily, 6-days a week, for a period of 6-months.

Main outcome variables

Serum ferritin will be assessed at baseline and after 6 months of therapy in terms of ng/ml and change in serum ferritin level will be calculated as difference in serum ferritin level obtained at two follow-up visits.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221231056999N2**
Registration date: **2023-07-25, 1402/05/03**
Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**
Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

M Aamir

Name of organization / entity

RESnTEC, Institute of Research

Country

Pakistan

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+92 321 6801143

Email address

aamir@resntec.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-02-28, 1402/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Oral versus Injectable Iron Chelation Therapy in Reducing Serum Ferritin Levels in Patients with Transfusion Dependent Thalassemia

Public title

Comparison of Oral versus Injectable Iron Chelation Therapy in Reducing Serum Ferritin Levels in Patients with Transfusion Dependent Thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presenting with beta thalassemia major (defined as group of hereditary disorders characterized by a genetic deficiency in the synthesis of beta-globin chains in blood causes severe, transfusion-dependent anemia). Patients who are transfusions dependent with serum ferritin level >2000 ng/ml.

Exclusion criteria:

Children already taking trial treatment (as per medical record). Children with liver failure (ALT & AST >50IU). Children having anemia (hemoglobin level <10 g/dl) Children who will lose during follow ups. Parents/Guardian refused the participation of their child. Stoppage of medicine due to side effects/compliance.

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Children will be randomly divided in two groups by using random number table that will be generated by using Microsoft Excel

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

Institutional Ethical Committee

Street address

Jampur Road

City

Dera Ghazi Khan

Postal code

32200

Approval date

2023-04-20, 1402/01/31

Ethics committee reference number

45-IEC-2032

Health conditions studied

1

Description of health condition studied

Beta thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Serum ferritin level

Timepoint

Assessed at baseline and after 6 months of therapy

Method of measurement

Blood sample will be taken by using 3cc disposable syringe and sent to the laboratory of the hospital for assessment of serum ferritin level using standard laboratory protocols.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children will be given oral iron chelation therapy i.e. daily Deferiprone at a dose of 75mg/kg/day in two to three divided doses, for a period of 6-months.

Category

Treatment - Drugs

2

Description

Control group: Children will be given injectable iron chelation therapy i.e. single dose of deferoxamine 4

mmol (225 mg) daily, 6-days a week, for a period of 6-months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Pediatric Medicine, DHQ Teaching Hospital, Dera Ghazi Khan

Full name of responsible person
Dr. Fatima Rafique

Street address
Jampur Road

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
None

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
RESnTEC, Institute of Research

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Position
Research Consultant

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available