

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 intervention 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 group) 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 intervention 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

Phone

+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

City

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Postal code

32200

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Email

aamir@resntec.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

DHQ Teaching Hospital

Full name of responsible person

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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

Full name of responsible person

M. Aamir

Position

Research Consultant

Latest degree

Bachelor

Other areas of specialty/work

Research Consultation

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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