

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Evaluating the effect of oral iron chelators on markers of renal function in beta-thalassemia major

Protocol summary

Study aim

Determination and comparison of mean kidney markers in β -thalassemic patients receiving deferasirox or deferoxamine and healthy control group

Design

non-randomized open-label controlled Clinical trial with parallel groups

Settings and conduct

The present study is conducted on children and adolescents over the age of 4 in three groups, Beta-thalassemia patients undergoing therapy for deferasirox, treated with deferoxamine, and a healthy control group in 17th Shahrivar children Hospital, Rasht

Participants/Inclusion and exclusion criteria

inclusion criteria beta thalassemia major patients receiving deferasirox for more than a year beta thalassemia major patients receiving deferoxamine for more than a year healthy control group exclusion criteria previous diagnosis of congenital diseases previous diagnosis of renal functions diseases acute sign and symptoms of acute kidney disease

Intervention groups

Deferasirox treatment Deferoxamine treatment

Main outcome variables

kidney function markers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090111001545N4**

Registration date: **2018-05-05, 1397/02/15**

Registration timing: **retrospective**

Last update: **2018-05-05, 1397/02/15**

Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Hamidreza Badeli

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-02-20, 1396/12/01

Trial completion date

empty

Scientific title

Evaluating the effect of oral iron chelators on markers of renal function in beta-thalassemia major

Public title

Evaluating the effect of oral iron chelators on markers of renal function in beta-thalassemia major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

beta thalassemia major patients receiving deferasirox for more than a year beta thalassemia major patients

receiving deferoxamine for more than a year healthy control group

Exclusion criteria:
previous diagnosis of congenital diseases previous diagnosis of renal functions diseases acute sign and symptoms of acute kidney disease

Age
From **4 years** old to **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **15**
Actual sample size reached: **15**

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

Ethics committee of guilan University of Medical Sciences

Street address

Siadati

City

Rasht

Province

Guilan

Postal code

4144444444

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

IR.GUMS.REC.1394.349

Health conditions studied

1

Description of health condition studied

Thalassaemia Major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

renal function markers

Timepoint

after on year treatment

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: treatment with defrasirox

Category

Treatment - Drugs

2

Description

Intervention group: treatment with defroxamine

Category

Treatment - Drugs

3

Description

Control group: healthy individuals

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Hamidreza Badeli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

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?**

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Hamidreza Badeli

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Web page address

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

regarding the ethical issues and confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available