Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 13 1322 9523

Email address
badeli@gums.ac.ir

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

Street address

Siadati

City

Rasht

Province

Guilan

Postal code

4144464444

Phone

+98 13 3336 9002

Email

badeli@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Shadman Nemati
Street address
Shahid Siadati Street
City
Rasht
Province
Guilan
Postal code
4144444444
Phone
+98 13 3336 9031
Email
research@gums.ac.ir
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
Street address
Siadati
City
Rasht
Province
Guilan
Postal code
4144444445
Phone
+98 13 3336 9002
Fax
+98 13 1322 6101
Email
badeli@gums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Hamidreza Badeli
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Soheil Medical Building, Golsar Cross
City
Rasht
Province
Guilan
Postal code
4144444445
Phone
+98 13 3336 9002
Fax
+98 13 3336 9061
Email
badeli@gums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Hamidreza Badeli
Position
Nephrologist and Associate Professor of Guilan University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Shahid Siadati Street
City
Rasht
Province
Guilan
Postal code
4144444444
Phone
+98 13 3336 9002
Fax

Email
badeli@gums.ac.ir
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