Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of deferasirox and deferiprone combination and defroxamine/deferiprone regimen among patients with beta-thalassemia

Protocol summary

Study aim

Comparison of the effect of deferasirox and deferiprone combination and defroxamine/deferiprone regimen on patients with beta-thalassemia

Design

This study will be conducted on β-thalassemia patients who are receiving deferoxamine plus deferiprone. 54 eligible patients will be randomly selected and randomly divided into two groups (27 patients in each group) . Patients in control group will receive deferoxamine + deferiprone and Patients in intervention group will receive deferasirox + deferiprone. The patients will be treated with these two regimens for at least 6 months. Monitoring of both groups will be done on a regular basis. Serum ferritin will be measured every three months. Cardiac MRI T2 * and the amount liver of iron will be measured before and after the study. All patients will be evaluated with the SF-36 questionnaire for measuring quality of life before and after the study.

Settings and conduct

54 patients with beta thalassemia who admitted to the thalassemia outpatient clinic at Tabriz Shahid Ghazi hospital will be selected randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patients with beta thalassemia who has beem referred to the outpatient clinic for routine blood transfusion and has receive deferoxamine+deferiprone Exclusion criteria: • Patients with hepatic impairment (ALT>5 times more than normal); Pregnancy; Patients with Renal impairment (GFR< 30 ml/min); Patients with chelating agent induced renal impairment

Intervention groups

Control group(27 patients): deferoxamine + deferiprone. Intervention group (27 patients): deferasirox + deferiprone. Serum ferritin will be measured every three months. Cardiac MRI T2 * and the amount liver of iron will be measured before and after the study. All patients will be evaluated with the SF-36 questionnaire for measuring quality of life before and after the study.

Main outcome variables

Ferritine level; MRI indinces; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160310026998N7**
Registration date: **2018-05-05, 1397/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-05, 1397/02/15**
Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Saba Ghaffary

Name of organization / entity

Faculty of Pharmacy, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 33266042

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ghaffarys@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of deferasirox and deferiprone combination and defroxamine/deferiprone regimen among patients with beta-thalassemia

Public title

Efficay comparison two oral chelators combination in patients with beta-thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

β thalassemia patients who have continuous blood transfusions receiving deferoxamine with deferiprone.

Exclusion criteria:

Patients who changes their chelator during the study. Patients who changes thier blood transfusion pattern during the study Patients with liver complications (rise of aminotransferase >5 times of baseline) Pregnant women Patients with renal insufficiency with a creatinine clearance (GFR) of less than 30 ml / min. patients with renal adverese effect of chelating agent (rise serum creatinine>2 time of baseline orproteinuria)

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

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 Tabriz University of Medical Sciences

Street address

Shahid ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

51665158

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.TBZMED.REC.1396.1239

Health conditions studied

1

Description of health condition studied

Two oral chelattor consumption in patients with beta thalassemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Ferritine level

Timepoint

baseline and after 6 months

Method of measurement

blood sample

2

Description

Quality of life

Timepoint

baseline and after 6 months

Method of measurement

Questionare

3

Description

MRI indinces

Timepoint

baseline and after 6 months

Method of measurement

MRI

Secondary outcomes

empty

Intervention groups

1

Description
Patients in intervention group will receive Deferasirox + Deferiprone. Deferiprone will be consumed with a previous dosage and deferasirox will be administered in a standard dosage range (20-40 mg/kg). patients will receive this combination regimen for 6 month. Chelators produced by Avecina and Osve company will be used.

Category
Treatment - Drugs

2

Description
Patients in control group will receive Deferoxamine + Deferiprone. Both will be consumed with a previous dosage. patients will receive this combination regimen for 6 month. Chelators produced by avecina and roonak daroo company will be used.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Thalassemia and Hemophilia out patient clinic of Tabriz Shahid Ghazi hospital

Full name of responsible person
Saba Ghaffary

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Saba Ghaffary

Position
Assistant professor

Latest degree
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Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact
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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
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