

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

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

Protocol summary

Study aim

Comparison of the effect of deferasirox and deferiprone combination and deferoxamine/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 been 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 indices; 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)

Phone

+98 33266042

Email address

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 deferoxamine/deferiprone regimen among patients with beta-thalassemia

Public title
Efficacy 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 adverse 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 indices
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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Daneshgah street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz 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

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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Daneshgah street

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