

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of oral administration of selenium on serum ferritin level and serum iron concentration in patients with Beta Thalassemia major

Protocol summary

Summary

In this study 34 chronically transfused Beta Thalassemia patients who are receiving Iron chelators will included. Patients whose iron chelators change during the study; Patients whose pattern of blood infusion changes during the study; Pregnant women; Patients with renal failure and creatinine clearance (GFR) lower than 30 ml/min will excluded from the study. Patients will take 200 micrograms of selenium supplement daily for one month. Blood sample will be taken from patients before intervention and afterwards at the end of the month. Serum level of ferritin, Iron, Glutation peroxidase and selenium will be measured at baseline and after a month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021226998N3**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-01, 1396/03/11

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

Shahid Ghazi hematology and oncology research center

Expected recruitment start date

2017-01-24, 1395/11/05

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral administration of selenium on serum ferritin level and serum iron concentration in patients with Beta Thalassemia major

Public title

Effects of oral administration of selenium on serum ferritin level and serum iron concentration in patients with Beta Thalassemia major

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Beta Thalassemia major
Exclusion criteria: Patients whose iron chelators change during the study; Patients whose pattern of blood infusion changes during the study; Pregnant women; Patients with renal failure and creatinine clearance (GFR) lower than 30 ml/min

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 34

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for Research (VCR) of Tabriz
University of Medical Sciences

Street address
Daneshgah street, Daneshgah square

City
Tabriz

Postal code

Approval date
2017-04-10, 1396/01/21

Ethics committee reference number
IR.TBZMED.REC.1396.13

Health conditions studied

1

Description of health condition studied
BetaThalassemia major

ICD-10 code
17

ICD-10 code description
ناهنجاری های مادرزادی، اختلال در شکل گیری و ناهنجاری های کروموزومی

Primary outcomes

1

Description
Ferritin

Timepoint
Before and after

Method of measurement
Laboratory blood test

Secondary outcomes

1

Description
Liver function test

Timepoint
1 month

Method of measurement
Laboratory blood test

Intervention groups

1

Description
Tablet selenium 200 microgram daily for one month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ghazi hospital

Full name of responsible person
Dr Saba Ghaffary

Street address
Shahid ghazi hospital, Daneshgah street, Daneshgah square

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hematology and Oncology research center, Tabriz
University of Medical Sciences

Full name of responsible person
Saba Ghaffary

Street address
Shahid ghazi hospital, Daneshgah street, Daneshgah square

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hematology and Oncology research center, Tabriz
University of Medical Sciences

Proportion provided by this source
100

Public or private sector

empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor of Clinical Pharmacy
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty