Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Labratory blood test

Secondary outcomes

1

Description
Liver function test
Timepoint
1 month
Method of measurement
Labratory 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

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 of Clinical Pharmacy

Other areas of specialty/work

Street address

Shahid ghazi hospital, Daneshgah street, Daneshgah square

City

Tabriz

Postal code

Phone

+98 41 3336 5010

Fax

Email

ghaffarys@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Saba Ghaffary

Position

Assistant Professor of Clinical Pharmacy

Other areas of specialty/work

Street address

Shahid ghazi hospital, Daneshgah street, Daneshgah square

City

Tabriz

Postal code

Phone

+98 41 3335 5010

Fax

Email

ghaffarys@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Saba Ghaffary

Position

Assistant Professor of Clinical Pharmacy

Other areas of specialty/work

Street address

Shahid ghazi hospital, Daneshgah street, Daneshgah square

City

Tabriz

Postal code

Phone

+98 41 3336 5010

Fax

Email

ghaffarys@tbzmed.ac.ir

Web page address

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