Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of supplementation with Selenium on serum inflammatory factors of beta thalassemia major patients.

Protocol summary

Study aim
The purpose of this study is to investigate the effect of supplementation with selenium antioxidant on inflammatory markers and neutrophil to lymphocyte ratio as a measure of immune system function in patients with thalassemia.

Design
Randomized 42 patients were studied. The sampling method will be both before and after supplemental therapy and fasting.

Settings and conduct
In a randomized clinical trial, 42 patients with thalassemia major or intermedia in Khuzestan province are selected from among those who refer to Baghaei 2 hospital in Ahvaz city. Selenium tablets of 200 µg are given to the patients daily for one month after receiving the first dose. At the beginning of the treatment, and one month after the start of the treatment, peripheral blood samples are taken from the patients and the main outcome variables are measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Having thalassemia major or intermedia • Healthy liver and kidney function Exit criteria: • Severe heart, liver, or kidney failure • History of chemotherapy • Diabetes patients • Patients with fever and acute and chronic inflammatory infections • Taking any selenium supplement at least two months before the study

Intervention groups
42 patients with thalassemia major or intermedia are selected according to the study criteria. Selenium tablets of 200 µg are given to the patients daily for one month after receiving the first dose. Inflammatory factors are measured before and after supplementation with selenium.

Main outcome variables
Determination of levels of IL-6, IL-1b, IL-2, TNF-a, CRP, neutrophil to lymphocyte ratio (N/L Ratio)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180603039959N3**
Registration date: **2023-02-06, 1401/11/17**
Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **2**

Registration date
2023-02-06, 1401/11/17

Registrant information

Name
bijan keikhaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3375 0410

Email address
keikhaeib@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-21, 1401/12/02

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of supplementation with Selenium on serum inflammatory factors of beta thalassemia major patients.

Public title
Investigation of the effect of Selenium in beta thalassemia major
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having thalassemia major or intermedia Healthy liver and kidney function
Exclusion criteria:
Severe heart, liver or kidney failure History of chemotherapy Diabetic patients Patients with fever and acute and chronic inflammatory infections Taking any selenium supplement for at least two months before the study
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **42**
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
Research Ethics Committees of Golestan Hospital
Street address
Golestan hospital, Farvardin Blvd, Golestan region
City
Ahvaz
Province
Khouzestan
Postal code
6138933333
Approval date
2022-11-14, 1401/08/23
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.140

Health conditions studied

1

Description of health condition studied
thalassemia major
ICD-10 code
D56.1
ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
TNF-alpha (TNF-a)
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure TNF-a.

2

Description
IL-6
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure IL-6.

3

Description
IL-1b
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure IL-1b.

4

Description
IL-2
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure IL-2.

5

Description
C-reactive protein (CRP)
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure CRP.

6

Description
Neutrophil to lymphocyte ratio (N/L Ratio)
Timepoint
Start of treatment, one month after treatment
Method of measurement
The ratio of neutrophils to lymphocytes (N/L ratio) is obtained from the results of complete blood count (CBC).

7

Description
The antioxidant superoxide dismutase (SOD)
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure SOD

8

Description
Thyroid Stimulating Hormone (TSH)
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure TSH

9

Description
Triiodothyronine (T3)
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure T3

10

Description
Thyroxine (T4)
Timepoint
Start of treatment, one month after treatment
Method of measurement
ELISA method is used to measure T4

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 42 patients with thalassemia major or intermedia are selected according to the study criteria. Selenium tablets of 200 µg are given to the patients daily for one month after receiving the first dose. Inflammatory factors are measured before and after supplementation with selenium.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan city hospitals
Full name of responsible person
Kambiz Davari
Street address
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۴۵۱۳۹۵۶۱۱۱
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+98 912 349 6607
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Kdatzums@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Baghaei 2 hospital Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Kambiz Davari
Position
assistant Hematology
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
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Person responsible for updating data

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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
There is no further information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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