

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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
Exclusion 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.

IR.AJUMS.HGOLESTAN.REC.1401.140

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 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

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

Zanjan city hospitals

City

Zanjan

Province

Zanjan

Postal code

۴۵۱۳۹۵۶۱۱۱

Phone

+98 912 349 6607

Email

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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Ahvaz

Province

Khouzestan

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61357-15794

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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
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Person responsible for scientific inquiries

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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