

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of Selenium supplementation therapy on the inflammatory markers oxidative stress and liver functional parameters in thalassemia major and intermediate

Protocol summary

Study aim

Evaluation of the efficacy of Selenium supplementation therapy on the inflammatory markers oxidative stress and liver functional parameters in thalassemia major and intermediate e in Zanzan province.

Design

The clinical trial has a community-based, practice-oriented one group, with group only

Settings and conduct

Eligible patients who have referred to the blood clinic of Ayatollah Mousavi Hospital in Zanzan will be included in the study. In these patients, in addition to routine treatments, they will take 200 micrograms of selenium tablets daily for 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Willingness to participate in the study 2. Having thalassemia major or intermedia 2. Having healthy liver and kidney function Exclusion criteria: 1. History of chemotherapy 2. Take any supplements and vitamins at least two months before the study 3. Diabetic patients 4. Patients with acute and chronic infections 5. Having any inflammatory disease

Intervention groups

A group will participate in this study. In addition to routine treatments, this group will take 200 micrograms of selenium tablets daily for 4 weeks.

Main outcome variables

Decreased inflammatory markers (ferritin and hCRP),
Decreased liver function parameters (AST and ALT),
Reduction of oxidative stress markers (Malondialdehyde)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210326050772N1**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Narges Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 9604

Email address

narges.heidari90@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Selenium supplementation therapy on the inflammatory markers oxidative stress and liver functional parameters in thalassemia major and intermediate

Public title

Evaluation of the efficacy of Selenium supplementation therapy on the inflammatory markers oxidative stress and liver functional parameters

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Having thalassemia major or intermedia Having healthy liver and kidney function

Exclusion criteria:

History of chemotherapy Take any supplements and vitamins at least two months before the study Diabetic patients Patients with acute and chronic infections Having any inflammatory disease

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Ethics Committee of Deputy of Research and Technology of Zanjan University of Medical Sciences

Street address

Deputy of Research and Technology, third floor, Second building, Central Headquarters of Zanjan University of Medical Sciences, The beginning of Jomhuri Eslami Boulevard, Azadi Blv, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.ZUMS.REC.1399.250

Health conditions studied

1

Description of health condition studied

Thalassemia major and intermedia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Inflammatory markers

Timepoint

Before the intervention and 30 days after the start of selenium consumption

Method of measurement

By measuring the inflammatory markers hCRP and ferritin

2

Description

Oxidative stress marker (Malondialdehyde)

Timepoint

Before the intervention and 30 days after the start of selenium consumption

Method of measurement

By measuring the oxidative stress markers (Malondialdehyde)

3

Description

Liver function parameters

Timepoint

Before the intervention and 30 days after the start of selenium consumption

Method of measurement

By measuring the liver function parameters (AST and ALT)

Secondary outcomes

empty

Intervention groups

1

Description

In these patients, in addition to routine treatments, they will take 200 micrograms of selenium tablets daily for 30 days.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**Ayatollah Mousavi Hospital in Zanjan and Al-Ghadir
Abhar Hospital**Full name of responsible person**

Dr. Kambiz Davari

Street addressAyatollah Mousavi Hospital, Gavazang Street, Soboti
Blv, Zanjan, Iran**City**

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4513956183

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Mousavihospital@zums.ac.ir

Web page addresshttp://zums.ac.ir/index.php?slc_lang=fa&sid=19**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

Street addressVice chancellor for research, Zanjan University of
Medical Sciences, Azadi Blvd. Zanjan**City**

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Research@zums.ac.ir

Web page addresshttp://zums.ac.ir/index.php?slc_lang=fa&sid=3**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Kambiz Davari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Web page addresshttp://zums.ac.ir/index.php?slc_lang=fa&sid=19**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr.kambiz Davari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Narges Heidari

Position

Pediatric student

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completing the study, there is a plan to share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patents, clinical reports, analysis codes, and data coding systems (Dictionary).

When the data will become available and for how long

The start of the access period to the data of this study will be from Early 2022 and approximately 6 months after the publication of the results.

To whom data/document is available

The data of this study are possible for all patients with thalassemia major and intermedia, and especially those working in health care systems.

Under which criteria data/document could be used

The researcher wants to use the data to improve major and intermedia Thalassemia.

From where data/document is obtainable

To receive information anyone can use the following email: Kddavari@zums.ac.ir, soltanpoorm@zums.ac.ir

What processes are involved for a request to access data/document

After sending the message and introducing herself or himself and the reason for the need for data, the applicant will be provided with the information after confirmation.

Comments