

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

To study the joint and separate effects of vitamin E and zinc supplementation on serum levels of vitamin E, zinc, and antioxidants in beta thalassemia major patients

Protocol summary

Summary

This double blind randomized clinical trial designed to determine the effects of zinc and vitamin E supplementation on oxidative stress in beta-thalassemic major patients. 120 beta thalassemic patients aged more than 18 years were randomly divided into four 30 subject groups to receive Zinc supplements 50 mg/day, vitamin E 400 mg/day, both of these supplements similar to mentioned dosages, or no supplements for 3 months. The effect of supplementations on serum zinc and vitamin E, superoxide dismutase, glutathione peroxidase, total antioxidant capacity, and body mass index were measured at the baseline and the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811033139N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Maryam Aboomardani

Name of organization / entity

Faculty of Health & Nutrition, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 2292

Email address

aboomardani@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Drug Applied Research Center & Nutrition Research Center of Tabriz University of Medical Sciences

Expected recruitment start date

2008-10-06, 1387/07/15

Expected recruitment end date

2009-02-08, 1387/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To study the joint and separate effects of vitamin E and zinc supplementation on serum levels of vitamin E, zinc, and antioxidants in beta thalassemia major patients

Public title

The effect of vitamin E and zinc supplementation on serum levels of vitamin E, zinc, and antioxidants in beta thalassemia major patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: history of continuous treatment with blood transfusion and desferal as a chellator agent.

Exclusion criteria: history of diabetes mellitus, smoking, hepatitis B and C and consumption of any supplements at least three month prior to the study.

Age

From **18 years** old to **43 years** old

Gender

Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Vice Chancellor of Tabriz University of Medical Sciences

Street address
University st., Golgasht st.

City
Tabriz

Postal code
5166614711

Approval date
empty

Ethics committee reference number
8732

Health conditions studied

1

Description of health condition studied
Beta Thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Cooley's anaemia, Severe beta thalassaemia

Primary outcomes

1

Description
Serum level of vitamin E

Timepoint
3 months

Method of measurement

Enzymatic analysis

2

Description
Serum level of zinc

Timepoint
3 months

Method of measurement
enzymatic analysis

3

Description
glutathion peroxidase activity

Timepoint
3 months

Method of measurement
enzymatic analysis

4

Description
Body mass index

Timepoint
3 months

Method of measurement
Dividing weight (kg) by the second power of height(m)

Secondary outcomes

1

Description
Appetite

Timepoint
3 months

Method of measurement
Questionnaire

2

Description
Wellbeing

Timepoint
3 months

Method of measurement
questionnaire

Intervention groups

1

Description
cotrol group which did not recieve any supplements

Category
N/A

2

Description
Zinc sulfate, 220mg daily, orally for three months

Category

Treatment - Drugs

3**Description**

Vitamin E, 400mg daily, orally for three months

Category

Treatment - Drugs

4**Description**

Vitamin E, 400mg daily and Zinc sulfate, 220mg daily, orally for three months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Hospitals- Thalassemia Section- Gorgan

Full name of responsible person

Dr. Narges Beigom Mirbehbehani

Street address

in front of Army Hospital- Army boulevard, Gorgan,Iran

City

Gorgan

2**Recruitment center****Name of recruitment center**

Amiralmomenin Hospital

Full name of responsible person

Dr Sadegh Ali Azimi

Street address

Amiralmomenin Hospital, End of park street, Kordkoy

City

Kordkoy

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Drug Applied Research Center, Nutrition Research Center, Tabriz University of Medical Science

Full name of responsible person

Dr. Hossein Babaei, Dr. Alireza Ostadrahimi

Street address

Nutrition Research Center, Faculty of Health & Nutrition, Atar-Neishaboori st, Golgasht st, Tabriz, Iran & University st. Pashmineh complex, Drug Applied Research Center

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Drug Applied Research Center, Nutrition Research Center, Tabriz University of Medical Science

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**

Nutrition Research Center of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Maryam Rafrat

Position

An academic member of Tabriz University of Medical Sciences/ph.D in Nutrition Science

Other areas of specialty/work**Street address**

Nutrition Research Center, Faculty of Health & Nutrition, Atar-Neishaboori st, Golgasht st, Tabriz, Iran

City

Tabriz

Postal code

5166614711

Phone

+98 41 1335 2292

Fax

+98 41 1336 3430

Email

rafrafm@tbzmed.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nutrition Research Center of Tabriz University of Medical Science

Full name of responsible person

Dr. Maryam Rafrat

Position

An academic member of Tabriz University of Medical sciences/ PhD in Nutrition Science

Other areas of specialty/work**Street address**

Nutrition Research Center, Faculty of Health & Nutrition, Atar-Neishaboori st, Golgasht st, Tabriz, Iran

City
Tabriz
Postal code
5166614711
Phone
+98 41 1335 2292
Fax
+98 41 1336 3430
Email
rafrafm@tbzmed.ac.ir
Web page address

Tabriz
Postal code
5166614711
Phone
+98 41 1335 2292
Fax
+98 41 1336 3430
Email
aboomardani@goums.ac.iraboomardani@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Health & Nutrition Faculty of Tabriz University of
Medical Sciences
Full name of responsible person
Dr. Maryam Aboomardani
Position
Ph.D student of Nutrition
Other areas of specialty/work
Street address
Nutrition Research Center, Faculty of Health &
Nutrition, Atar-Neishaboori st, Golgasht st, Tabriz, Iran
City

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