Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 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 boulvard, 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 Scienes
Full name of responsible person
Dr. Maryam Rafraf
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 Rafraf
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

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