

# 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

control group which did not receive 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 &amp; Nutrition, Atar-Neishaboori st, Golgasht st, Tabriz, Iran &amp; 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 &amp; 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

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**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*