

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Sep 2026

### Effect of green tea consumption on iron stores, metabolic and oxidative status in beta-thalassemia major patients

#### Protocol summary

##### Summary

Objective: Effects of green tea consumption on iron stores, metabolic and oxidative status in beta-thalassemia major. Design: This study is designed as a randomized clinical, not blinded and phase 3 trial in patients with thalassemia major who will be referred the Tabriz Ghazi Tabatabaei hospital. Inclusions criteria: Including beta-thalassemia disease, usage of chelator drug deferoxamine, not suffering from viral hepatitis B and C, having over 18 years of age and not use of any antioxidant supplements 3 months before intervention. Absence of any of the above conditions will result in withdrawal from the study subjects. 52 patients (sample size) will be divided into 2 groups randomly, intervention and control. Intervention: Intervention groups will receive daily 3 cups of green tea (each cups contain a 2.5 grams of green tea bag in 150 cc boiled water) immediately after the meal for 8 weeks and control group use the same amount of boiled water daily instead of green tea in this period. Outcome: Iron stores levels (Iron serum, Ferritin serum, Transferrin Saturation and TIBC), liver enzymes (AST, ALT), lipid profiles (Total cholesterol, Triglyceride, HDL-C and LDL-C) and indicators of oxidative stress (total antioxidant capacity and malondialdehyde) in both groups before and after the intervention will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201403303664N10**

Registration date: **2014-11-29, 1393/09/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-29, 1393/09/08

##### Registrant information

###### Name

Maryam Rafrat

###### Name of organization / entity

Tabriz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7580

###### Email address

rafrafm@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-11-22, 1393/09/01

##### Expected recruitment end date

2015-02-20, 1393/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of green tea consumption on iron stores, metabolic and oxidative status in beta-thalassemia major patients

##### Public title

Effect of green tea consumption in the treatment of patients with beta-thalassemia major

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Beta-thalassemia disease; usage of

chelator drug deferoxamine; not suffering from viral hepatitis B and C; having over 18 years of age and not use of any antioxidant supplements 3 months before intervention. Exclusion criteria: Absence of any of the above conditions will result in withdrawal from the study subjects

#### **Age**

From **18 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **52**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

##### **Street address**

Science Medical of University Tabriz of department Central, Street Azadi, Street Golgasht, Tabriz

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2014-05-18, 1393/02/28

#### **Ethics committee reference number**

9327

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Beta thalassaemia

#### **ICD-10 code**

D56.1

#### **ICD-10 code description**

Beta thalassaemia

## **Primary outcomes**

### **1**

#### **Description**

Iron stores levels ( Iron serum, Ferritin serum, Transferrin Saturation and TIBC)

#### **Timepoint**

Baseline and after 8 weeks of intervention

#### **Method of measurement**

Spectrophotometry for Iron serum and TIBC, ELISA assay for ferritin and Iron serum/TIBC\* 100 for Transferrin Saturation

### **2**

#### **Description**

liver enzymes (AST, ALT)

#### **Timepoint**

Baseline and after 8 weeks of intervention

#### **Method of measurement**

Spectrophotometry

### **3**

#### **Description**

Lipid profiles (TC, TG, LDL-C, HDL-C)

#### **Timepoint**

Baseline and after 8 weeks of intervention

#### **Method of measurement**

Enzymatic methods for TC,TG and HDL-C For LDL-C :  
Freidwald's formula:  $LDL-C = TC - HDL-C - (TG/5)$

### **4**

#### **Description**

Serum Total Antioxidant Capacity

#### **Timepoint**

Baseline and after 8 weeks of intervention

#### **Method of measurement**

Spectrophotometry

### **5**

#### **Description**

Serum Malondialdehyde (MDA)

#### **Timepoint**

Baseline and after 8 weeks of intervention

#### **Method of measurement**

Spectrophotometry

## **Secondary outcomes**

### **1**

#### **Description**

Macronutrients intake

#### **Timepoint**

Before and after 8 weeks intervention

#### **Method of measurement**

24-h Recall Questionnaire

## 2

### **Description**

Anthropometric index(weight and Body Mass Index)

### **Timepoint**

Before and after 8 weeks intervention

### **Method of measurement**

Analogue scale for weight and weight (Kg) /Square  
Height for Body Mass Index

## **Intervention groups**

### 1

#### **Description**

Intervention group will receive daily 3 cups of green tea immediately after the meal for 8 weeks (each cup of green tea is produced by putting green tea bag contains 2.5 grams in 150 cc of boiled water). Green tea bags will be purchased from the tea Research Center in North. All the patients will receive the Tea bags on every two weeks base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group 3 cups lukewarm boiled water daily over the same period (per cup after meal consumption).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Tabriz Qazi Tabatabaei hospital

##### **Full name of responsible person**

Ehsan Soeizi

##### **Street address**

Next to the School of Dentistry, University Ave, Tabriz

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Tabriz University of  
Medical Science

##### **Full name of responsible person**

Dr Bahram Pourghasem Gagari

##### **Street address**

Tabriz University of Medical Science, Golgasht Street,  
Azadi Street, Tabriz

##### **City**

Tabriz

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Vice chancellor for research, 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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Ehsan Soeizi

##### **Position**

MSc student of nutrition

##### **Other areas of specialty/work**

##### **Street address**

Science Medical of University of Tabriz of faculty  
Nutrition, Golgasht Street, Tabriz

##### **City**

Tabriz

##### **Postal code**

##### **Phone**

+98 41 3656 0683

##### **Fax**

##### **Email**

Esoeizi@gmail.com

##### **Web page address**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Ehsan Soeizi

##### **Position**

MSc student of nutrition

##### **Other areas of specialty/work**

##### **Street address**

Science Medical of University Tabriz of faculty Nutrin,  
Golgasht Street, Tabriz

##### **City**

Tabriz

##### **Postal code**

**Phone**  
+98 41 3656 0638  
**Fax**  
**Email**  
Esoeizi@gmail.com  
**Web page address**

**Phone**  
+98 41 3656 0638  
**Fax**  
**Email**  
Esoeizi@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Ehsan Soeizi  
**Position**  
MSc student of nutrition  
**Other areas of specialty/work**  
**Street address**  
Science Medical of University Tabriz of faculty  
Nutrition, Golgasht street, Tabriz  
**City**  
Tabriz  
**Postal code**

## 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*