

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

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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

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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