Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of Green tea and black tea on the Iron overload in patients with thalassemia major

Protocol summary

Study aim
Comparison of the effect of green tea and black tea on the iron overload in patients with thalassemia major

Design
Randomized controlled clinical trial with two intervention groups, parallel groups, without blinding, phase 4 on 75 patients, randomized using table of random numbers.

Settings and conduct
This clinical trial study was performed on 75 patients with thalassemia major treated with blood transfusion in Zabol city who had the criteria to enter the study. Samples were randomly divided into three groups. First, patients' serum ferritin levels were measured. Intermediate consumption of green or black tea, 2 grams of tea provided by the researcher, three times a day, after each main meal was performed for one month, and patients' serum ferritin levels were measured again after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 8 and 20 years; Frequent blood transfusions; Ferrtin serum levels above 1000 ng / dL. Exclusion criteria: sensitivity to tea; diseases such as stomach ulcers that are exacerbated by tea consumption.

Intervention groups
The intervention was performed in two groups. Intervention group 1: green tea. Intervention group 2: black tea. In both groups 2 grams of tea was given for 1 month on a daily basis after each meal. No intervention was made in the control group.

Main outcome variables
Iron overload depletion; iron accumulation in different parts of the body

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200606047670N1**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **retrospective**

Last update: **2020-07-06, 1399/04/16**
Update count: **0**

Registration date
2020-07-06, 1399/04/16

Registrant information

Name
sadegh dehghanmehr

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-10, 1396/03/20

Expected recruitment end date
2017-07-23, 1396/05/01

Actual recruitment start date
2017-06-10, 1396/03/20

Actual recruitment end date
2017-07-23, 1396/05/01

Trial completion date
2018-01-02, 1396/10/12

Scientific title
Comparative study of the effect of Green tea and black tea on the Iron overload in patients with thalassemia major

Public title

Comparative study of the effect of Green tea and black tea on the Iron overload in patients with thalassemia major

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having thalassemia major and 2 blood transfusions per month for treatment not suffering from metabolic diseases and cancer willingness to participate in the study serum ferritin level above 1000 micrograms per liter

Exclusion criteria:

Eat foods rich in polyphenols such as chocolate and coffee over the past week Allergies and allergies to a variety of teas Illnesses such as stomach ulcers that can be exacerbated by tea consumption

Age

From **8 years** old to **20 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Simple Randomization, Randomization Unit: Individual and Instrumental Random Tools: Using Lottery.Write from 1 to 75 on small pieces of paper and put them in a bag, and each research unit takes a piece of paper at random without reading the written number. Then patients 1 to 25 were in the intervention group 1, patients from the 26th to the 50th intervention 2 and the rest up to 75 were in the control group.

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 Zabol University of Medical Sciences

Street address

Health Crossroads

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861844863

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ZBMU.REC.1396.68

Health conditions studied

1

Description of health condition studied

thalassemia major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Serum ferritin levels more than 1000 ng / dL

Timepoint

Measurement of serum ferritin at the beginning of the study and 30 days after tea consumption

Method of measurement

Eliza Method and Tecan a-55-82 machin

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention: Green tea was consumed 2 grams daily after each meal for 1 month, prepared and packed by the researcher from reputable stores.

Category

Treatment - Other

2

Description

Intervention group: Intervention 2: black tea 2 grams per day after each meal for 1 month prepared and packed by the researcher from reputable stores.

Category

Treatment - Other

3

Description
Control group: No intervention was performed for the control group, and patients received their routine treatment as usual.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Special Diseases Center
Full name of responsible person
Dr. Mirzaie
Street address
Hospital Crossroads
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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safora3405@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zabol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
To help reduce the iron Overload and its side effects in patients, and for other researchers to use this study for future studies.

When the data will become available and for how long
After printing the information in the articles

To whom data/document is available
Interested in all people including researchers, patients and others

Under which criteria data/document could be used
For new studies - if the data is not used exactly.

From where data/document is obtainable
To sadeghdehghan3407@gmail.com

What processes are involved for a request to access data/document
The reason for using the documents and how to conduct the study should be clearly stated in the application.

Comments