Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of curcumin supplementation on iron overload, oxidative stress and insulin resistance in patients with beta thalassemia major

Protocol summary

Summary

This study is a randomized double-blind placebo controlled trial in 64 patients with beta thalassemia major. The objective of the study is to determine the effects of curcumin supplementation on iron overload, oxidative stress and insulin resistance in patients with beta thalassemia major. The inclusion criteria is: age between 18 and 40, consumption of deferoxamine as an iron chelator drug, patients without hepatitis B, C and HIV, Not taking any nutritional supplements from 3 months before the start of the study and the exclusion criteria is: A significant change in dose of deferoxamine therapy during the study and pregnancy. A general questionnaire and 3-day, 24-hour dietary recalls will be completed for each subject at the beginning of the study. After matching according to sex and age the subjects will be randomly assigned to intervention and placebo group. Fasting blood sample (5 cc) will be obtained from each patient at the beginning of the study for measuring parameters such as serum iron, hemoglobin, ferritin, hepcidin, Non-transferrin-bound Iron, malondialdehyde, serum total antioxidant capacity,catalase, glucose and insulin. Then Patients in intervention group will take 2 curcumin capsules per day (each containing 500 mg curcuminoids) for 12 weeks and patients in placebo group will take 2 placebo capsules daily for 12 weeks. Patients and researchers will keep blind during the study. At the end of the study food intake will be evaluated again and blood sampling will be obtained again for measuring biochemical parameters

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053028165N1**
Registration date: **2016-06-30, 1395/04/10**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-06-30, 1395/04/10

Registrant information

Name

Esmat Nasseri

Name of organization / entity

National Nutrition and Food Technology Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7486

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esm_nasseri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

National Nutrition And Food Technology Research Institute, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of curcumin supplementation on iron overload, oxidative stress and insulin resistance in patients with beta thalassemia major

Public title

Effect of curcumin supplement in patients with beta

thalassemia major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 and 40, Regular blood transfusions based on prescription, consumption of deferoxamine as an iron chelator drug, Not taking any nutritional supplements from 3 months before the start of the study, patients without hepatitis B, C, HIV and chronic kidney and heart diseases, not using other chelator medication except deferoxamine. Excluson criteria: A significant change in dose of deferoxamine therapy during the study, using another iron chelator drug in addition to deferoxamine and pregnancy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of National Nutrition and Food Technology Research Institute

Street address

No.7, West Arghavan Ave.,Farahzadi Blvd.,Qods Town, Tehran

City

Tehran

Postal code

1981619573

Approval date

2015-10-19, 1394/07/27

Ethics committee reference number

IR.SBMU.nnftn.Rec.1394.18

Health conditions studied

1

Description of health condition studied

Beta thalassemia major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Hemoglobin

Timepoint

Before the study and after the study

Method of measurement

Cyanmethemoglobin method

2

Description

Serum iron

Timepoint

Before the study and after the study

Method of measurement

Spectrophotometry

3

Description

Ferritin

Timepoint

Before the study and after the study

Method of measurement

Elisa

4

Description

Hepcidin

Timepoint

Before the study and after the study

Method of measurement

Elisa

5

Description

Non-transferrin-bound iron

Timepoint

Before the study and after the study

Method of measurement

HPLC

6

Description

Malondialdehyde

Timepoint

Before the study and after the study

Method of measurement

Spectrophotometry

7

Description

Serum total antioxidant capacity

Timepoint

Before the study and after the study

Method of measurement

FRAP

8

Description

Catalase

Timepoint

Before the study and after the study

Method of measurement

Spectrophotometry

9

Description

Glucose

Timepoint

Before the study and after the study

Method of measurement

Enzymatic method

10

Description

Insulin

Timepoint

Before the study and after the study

Method of measurement

Elisa

11

Description

Insulin resistance

Timepoint

Before the study and after the study

Method of measurement

Calculation by using formula

Secondary outcomes

1

Description

Weight

Timepoint

before the study and after the study

Method of measurement

Scale

2

Description

Body mass index (BMI)

Timepoint

Before the study and after the study

Method of measurement

Calculation by using formula

Intervention groups

1

Description

Intervention group will take 2 curcumin capsules per day (each containing 500 mg curcuminoids) for 12 weeks

Category

Treatment - Drugs

2

Description

Control group will take 2 placebo capsules daily for 12 weeks. Placebo capsules are similar in size and color to the curcumin capsules

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Thalassemia Center

Full name of responsible person

Mina Abdollahzadeh

Street address

Amirkola Thalassemia Center, Amirkola, Babol, Mazandaran

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr Morteza Abdollahi

Street address

No.7,West Arghavan Ave.,Farahzadi Blvd.,Qods Town,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition and Food Technology Research

Institute

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

National Nutrition and Food Technology Research Institute

Full name of responsible person

Elahe Mohammadi

Position

PhD Candidate in Nutrition

Other areas of specialty/work

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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