Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of oral quercetin supplement intake on oxidative markers , serum iron, liver enzymes and inflammatory indices in β-thalassemia major patients,a double-blind placebo-controlled clinical trial

Protocol summary

Summary

The aim of this study is to determine the effect of oral quercetin supplement intake on oxidative markers , serum iron, liver enzymes and inflammatory indices in β-thalassemia major patients. 84 beta thalassemia major patieents, 18 to 30 years old with serume ferritin level between 2500 to 3500 ng/ml and iron chelation therapy with desferrioxamine will be enrolled and allocated double-blinded and randomly to the quercetin or the placebo group. The quercetin group will recieve a 500 mg quercetin tablet each day and the placebo group will recieve a 500 mg starch tablet each day for 3 months. There will be two blood specimen collection before and after the intervention to measure Malondialdehyde (MDA), Super Oxide Dismutase (SOD) and Glutathione peroxidase (GPx), total antioxidant capacity (TAC) as the primary outcomes and serum iron, ferritin, transferrin, total iron binding capacity (TIBC), transferrin saturation (TS), Alanine transaminase (ALT), Aspartate transaminase (AST), Alkaline phosphatase (ALP), high-sensitivity C-reactive protein (hs-CRP) and tumor necrosis factor (TNF) as the secondry outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701172709N43**
Registration date: **2017-04-13, 1396/01/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-13, 1396/01/24

Registrant information

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Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Iran University of Medical Siences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral quercetin supplement intake on oxidative markers , serum iron, liver enzymes and inflammatory indices in β-thalassemia major patients,a double-blind placebo-controlled clinical trial

Public title

Quercetin in thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 30 year old male and female beta

thalassemia major patients; Inclination to cooperate and signing the written informed consent; A minimum of 2 years of blood transfusion history; blood specimen collection 20 days after the last blood transfusion; Regular and peculiar iron-chelating therapy with desferrioxamine; Vitamin C supplement intake with desferrioxamine; Serum ferritin level between 2500 to 3500 ng/ml Exclusion criteria: Uncontrollable and life threatening complication due to due to the supplement intake; A change in type or amount of the iron chelator; Pregnancy or lactation; Splenectomy; Hepatitis infection and other metabolic or infectious diseases; Less than 80% compliance of supplement intake; Consumption of drugs that interfere with quercetin; Drinking more than 500 mg/day of beverages rich in flavonoids; Smoking or alcohol consumption

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The method of "permuted block randomization" will be used for the randomization.

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
before the Chamran intersection, East Hemmat highway,Tehran

City
Tehran

Postal code

Approval date
2017-01-16, 1395/10/27

Ethics committee reference number
IR.IUMS.REC 1395.9411323006

Health conditions studied

1

Description of health condition studied
beta thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Cooley anaemia Severe beta thalassaemia Thalassaemia: intermedia major

Primary outcomes

1

Description
malone dialdehyde (MDA)

Timepoint
before and after the intervention

Method of measurement
nmol/gHb, colorimetry

2

Description
total antioxidant capacity (TAC)

Timepoint
before and after the intervention

Method of measurement
mmol/L, colorimetry

3

Description
Superoxide dismutase (SOD)

Timepoint
before and after the intervention

Method of measurement
U/gHb, colorimetry

4

Description
Glutathione peroxidase (GPx)

Timepoint
before and after the intervention

Method of measurement
U/gHb, colorimetry

Secondary outcomes

1

Description

serum Fe
Timepoint
before and after the intervention
Method of measurement
spectrophotometry,µg/dl

2

Description
serum transferrin
Timepoint
before and after the intervention
Method of measurement
immunoturbidometry, mg/dl

3

Description
serum ferritin
Timepoint
before and after the intervention
Method of measurement
spectrophotometry, ng/ml

4

Description
total antioxidant capacity (TIBC)
Timepoint
before and after the intervention
Method of measurement
calorimetry, µg/dl

5

Description
transferrin saturation
Timepoint
before and after the intervention
Method of measurement
formula, %

6

Description
Aspartate transaminase (AST)
Timepoint
before and after the intervention
Method of measurement
enzymatic calorimetry, IU/L

7

Description
Alanin transaminase (ALT)
Timepoint
before and after the intervention
Method of measurement
enzymatic calorimetry, IU/L

8

Description
Alkaline phosphatase (ALP)
Timepoint
before and after the intervention
Method of measurement
enzymatic calorimetry, IU/L

9

Description
high-sensitivity C reactive protein (hs-CRP)
Timepoint
before and after the intervention
Method of measurement
ELISA, µg/ml

10

Description
tumor necrosis factor alpha (TNF)
Timepoint
before and after the intervention
Method of measurement
Elisa, pg/ml

Intervention groups

1

Description
quercetin,90 tablets,500mg,3 months, once a day after a meal
Category
Treatment - Drugs

2

Description
starch placebo, 90 tablets,500 mg, 3 months, once a day after a meal
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Adult Thalassemia Clinic
Full name of responsible person
Street address
Ladan square, Zafar avenue, Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Iran Thalassemia Community
Full name of responsible person
Street address
Number 22, Keshavarz Boulevard, Valiasr avenue,

Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Morteza Naser Bakht

Street address

before the Chamran intersection, East Hemmat highway,Tehran

City

Tehran

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, Iran University of Medical Sciences

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

High Institute for Research and Education in Transfusion Medicine

Full name of responsible person

Dr. Azita Azarkeivan

Position

Pediatric Hematology Oncology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Farzad Shidfar

Position

PHD of Nutrition Sciences

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Zohreh Sajady Hezaveh

Position

M.Sc. student of Health in Nutrition

Other areas of specialty/work

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zohre_sjd@yahoo.com

Web page address

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