

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Study of the effect of oral quercetin supplement intake on mood in β -thalassemia major patients

Protocol summary

Study aim

Determination and comparison of mood score based on the Beck questionnaire between the Quercetin group and the placebo at the end of the intervention and within each group before and after the intervention

Design

In this research, 84 eligible patients referring to Zafar Thalassemia Clinic were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This clinical trial will be held in Zafar thalassemia clinic. 84 eligible patients will be chosen and allocated randomly to the quercetin or the placebo group. The quercetin group will receive a 500 mg quercetin tablet each day and the placebo group will receive a 500 mg starch tablet each day for 3 months this is a double blind trial and neither the researcher nor the patients will be aware of the supplement being placebo or quercetin. once before and once after the intervention Beck's questionnaire will be filled to determine mood changes.

Participants/Inclusion and exclusion criteria

84 beta thalassemia major patients will be enrolled in this study. Inclusion criteria: 18 to 40 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 Exclusion criteria: A change in type or amount of the iron chelator Pregnancy or lactation 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

Intervention groups

There will be two interventional groups: 42 patients in the quercetin group will receive a 500 mg quercetin tablet each day and 42 patients in the placebo group will receive a 500 mg starch tablet each day for 3 months

Main outcome variables

mood changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N46**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **retrospective**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-22, 1396/02/02

Expected recruitment end date

2017-10-24, 1396/08/02
Actual recruitment start date
2017-04-22, 1396/02/02
Actual recruitment end date
2017-12-13, 1396/09/22
Trial completion date
empty
Scientific title
Study of the effect of oral quercetin supplement intake on mood in β -thalassemia major patients

Public title
Quercetin on thalassemia induced depression

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 40 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

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 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 **40 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
Actual sample size reached: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of "permuted block randomization" will be used for the randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
the researcher, participants, practitioner, and the statistical analyzer were all blinded in this study, which means non of them were aware of the supplement given to and consumed by patients were Quercetin or placebo.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

After the Chamran Intersection, East Hemmat Highway

City

Tehran

Province

Tehran

Postal code

88654

Approval date

2017-01-20, 1395/11/01

Ethics committee reference number

IR.IUMS.REC 1395.95-04-207-30254

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

depression

Timepoint

before and after the intervention

Method of measurement

Beck's questionnaire

Secondary outcomes

1

Description

high-sensitivity C-reactive protein(hs-CRP)

Timepoint

before and after the intervention

Method of measurement

using ELISA kit in Microgram/milliliter(micg/ml)

2

Description

Tumor necrosis factor α (TNF- α)

Timepoint

before and after the intervention

Method of measurement

using ELISA kit in Picrogram/milliliter(pg/ml)

Intervention groups

1

Description

Intervention group: a group of 42 thalassemia patients recieved quercetin tablets.They consumed one tablet containing 500 mg quercetin after lunch every day for 3 months and they were given information on possible side effects.

Category

Treatment - Drugs

2

Description

Control group: a group of 42 thalassemia patients recieved placebo tablets.They consumed one tablet containing 500 mg starch, cellulose, etc. after lunch every day for 3 months and they were given information on possible side effects.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

zafar thalassemia clinic

Full name of responsible person

Dr. Amirhossein Tarvand

Street address

Ladan square, Zafar avenue, Tehran

City

Tehran

Province

Tehran

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19541

Phone

+98 21 2292 0088

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info@tehranbtc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malakooti

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Blood Transfusion Education & Research Institute.

Full name of responsible person

Dr Azita Azarkeivan

Position

Children's Hematology and Oncology

Latest degree

Subspecialist

Other areas of specialty/work

Thalassemia

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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
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

after making the participants unrecognizable, some personal data like age, marital status, etc. will be shared to control the confounders.

When the data will become available and for how long

the access period starts a year after printing the results

To whom data/document is available

Researchers and students who need the data for their research projects.

Under which criteria data/document could be used

The use of this study's data is subject to the permission of all project partners. All statistical analyses can be implemented on the data.

From where data/document is obtainable

Dr Farzad Shidfar, School of Paramedical Sciences, Iran university of Medical Sciences

What processes are involved for a request to access data/document

If Dr. Shidfar permits, In less than a month, this study's data will be sent to the requestor in a SPSS file via email.

Comments