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 recieve a 500 mg quercetin tablet each day and the placebo group will recieve 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 recieve a 500 mg quercetin tablet each day and 42 patients in the placebo group will recieve 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
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Iran (Islamic Republic of)
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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
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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
before the Chamran intersection, East Hemmat highway
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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, marrital 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 thana month, this study's data will be sent to the requestor in a SPSS file via email.
Comments