Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effects of curcumin on GDF15 gene expression and iron status in patients with beta-thalassemia intermedia

Protocol summary

Study aim
Determining the effects of curcumin on GDF15 gene expression and iron status in patients with beta-thalassemia intermedia

Design
A clinical trial with two groups of treatment and placebo, double-blind, randomized, phase 2-3 on 30 patients with beta-thalassemia intermedia, was selected to randomized by simple randomisation method (using a card).

Settings and conduct
patients will be divided into two groups of treatment and placebo. In this study, which will be performed double blind, physicians and patients are not aware of the distribution and taking medication or placebo. The sampling place will be Imam Reza Clinic in Shiraz. At first, 5 cc of blood is taken from the patients and after a three-month period of taking the drug or placebo, the patients will be sampled again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: insensitivity to turmeric compounds, male gender, confirmation of beta-thalassemia intermedia by the relevant physician. Exclusion criteria: diabetes, cardiovascular disease, gallbladder remove.

Intervention groups
The treatment group took 500 mg of curcumin at a dose of 1,500 mg for three months under the supervision of a physician. The placebo group also receives the same amount of placebo in the form of 500 mg capsules with the same dose and shape of the treatment group.

Main outcome variables
Serum levels of iron, C-Reactive Protein and ferritin

General information

Reason for update
A sampling of patients was after receiving the code of ethics but before receiving the code of intervention.

Acronym

IRCT registration information
IRCT registration number: **IRCT20190902044668N1**
Registration date: **2020-08-10, 1399/05/20**
Registration timing: **retrospective**

Last update: **2020-09-22, 1399/07/01**
Update count: **1**

Registration date
2020-08-10, 1399/05/20

Registrant information

Name
Mohammadreza saeidnia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 84 3333 8392

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-19, 1399/01/31

Expected recruitment end date
2020-07-18, 1399/04/28

Actual recruitment start date
2020-04-19, 1399/01/31

Actual recruitment end date
2020-07-18, 1399/04/28

Trial completion date
2020-07-18, 1399/04/28

Scientific title
Evaluation of the effects of curcumin on GDF15 gene expression and iron status in patients with beta-thalassemia intermedia

Public title
effects of curcumin on beta-thalassemia intermedia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
gender male Lack of sensitivity to turmeric compounds The beta-thalassemia intermedia is approved by the doctor.
Exclusion criteria:
Cardiovascular disease Diabetes Gallbladder removal
Age
From **18 years** old to **35 years** old
Gender
Male

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Blood sampling in two stages before and after treatment at a rate of 5 cc
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
15 cards with the intervention group code label and 15 cards with the placebo group code label were placed inside the sealed envelopes and each patient was asked to choose randomly one of these envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs were distributed to patients in unlabeled sealed paper bags. The main drug and the placebo drug are both taken from the pharmaceutical company, which are similar in shape, size, and color. The difference between the main drug and the placebo was not clear to the participants, The project manager will know the arrangement of the main drug and placebo.
Placebo
Used
Assignment
Parallel
Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Meshkin Fam St. Paramedical School
City
Shiraz
Province
Fars
Postal code
71439-14693
Approval date
2020-04-19, 1399/01/31
Ethics committee reference number
IR.SUMS.REC.1399.124

Health conditions studied

1

Description of health condition studied
Intermediate beta-thalassemia
ICD-10 code
D56.1
ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Serum iron
Timepoint
At the beginning of the study (before the intervention) and three months after the start of curcumin intake
Method of measurement
Atomic absorption spectrometry, ELISA kit

Secondary outcomes

1

Description
Serum ferritin concentrations
Timepoint
At the beginning of the study (before the intervention) and three months after the start of curcumin intake
Method of measurement
ELISA

2

Description
C-reactive protein (CRP)
Timepoint
At the beginning of the study (before the intervention) and three months after the start of curcumin intake
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Curcumin; Each dose contains 450 mg of turmeric rhizome powder and 50 mg of turmeric extract, which is standardized based on 5.47 mg of curcumin. three months; Three doses per day orally; Dineh Pharmaceutical Company, Iran.
Category
Treatment - Drugs

2

Description
Control group: Placebo; Each dose contains 500 mg of starch or flour. three months; Three doses per orally; Dineh Iran Pharmaceutical Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic in Shiraz
Full name of responsible person
Dr. Mehran Karimi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
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Grant name
no
Grant code / Reference number
ندارد
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Gholamhossein Tamaddon
Position
Assistant Professor
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Other areas of specialty/work
Hematology
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Person responsible for scientific inquiries

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Student

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

Statistical Analysis Plan
Not applicable

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

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

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

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