

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of oral curcumin on liver enzymes and liver T2*MRI in patients with major and intermediate thalassemia

Protocol summary

Study aim

Evaluation of the effect of oral curcumin on liver enzymes and liver T2*MRI in patients with major and intermediate thalassemia

Design

Clinical trials with control group, randomized assignment to intervention and control groups, double blind study, with a sample size of 80

Settings and conduct

This clinical trial study will carry out in patients with major and intermediate thalassemia referred to Ali Asghar Children's Hospital. The patients will be coded according to the order of entry and randomly divided into two groups of intervention and the control group. The intervention group will receive the Curcumin tablet. The control group will receive the placebo. All subjects entering the trial will be checked in terms of the level of liver enzymes including bilirubin, ALT, AST, ALP and ferritin. Liver T2 * MRI will be performed at the beginning and end of the study. Patients will be monitored for 6 months by measuring their level of liver enzymes on a monthly basis and will be compared in two groups at the end of 6 months.

Participants/Inclusion and exclusion criteria

Entry requirements: All patients with major and intermediate thalassemia. Exit conditions: Parental dissatisfaction; Renal failure; Hepatitis B; Hepatitis C; AIDS

Intervention groups

The intervention group will receive curcumin oral tablet. The control group will receive placebo.

Main outcome variables

Alanine Aminotransferase Alkaline Phosphatase Aspartate Aminotransferase Total Bilirubin Direct Bilirubin ferritin liver T2*MRI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201107049296N1**

Registration date: **2021-08-31, 1400/06/09**

Registration timing: **prospective**

Last update: **2021-08-31, 1400/06/09**

Update count: **0**

Registration date

2021-08-31, 1400/06/09

Registrant information

Name

Aziz Eghbali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2268 8027

Email address

eghbali.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral curcumin on liver enzymes and liver T2*MRI in patients with major and intermediate thalassemia

Public title

Evaluation of the effect of oral curcumin on liver enzymes and liver T2*MRI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with major and intermediate thalassemia

Exclusion criteria:

Parental dissatisfaction Renal failure Hepatitis B Hepatitis C AIDS

Age

From 5 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

- A number plate or sheet is made for the total number of people in the case and control groups (numerical code from 1 to N). - All plaques are placed in an opaque bag. - Considering that half of the subjects are as Intervention group population and the other half are as the control group population, Half of the plaques are removed from the bag by drawing lots (based on the probabilistic sampling principles). The number of these plaques is considered as the code of the people receiving the real medicine and this code is also included on the real medicine packages. Obviously, the other codes will be related to the controls and placebo packages.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, only the main executor of the project will know the type of medication each patient receives, and by the end of the test, neither patient nor physician will know which patient is receiving medication or placebo. This will be done through the coding of patients and drugs. Meaning of the codes will be recognizable only to the main executor of the project.

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

Iran university of medical science., Next to Milad Tower., Hemmat Highway., Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-09-29, 1399/07/08

Ethics committee reference number

IR.IUMS.REC.1399.627

Health conditions studied

1

Description of health condition studied

Thalassemia

ICD-10 code

D56

ICD-10 code description

Thalassemia

Primary outcomes

1

Description

Alanine Aminotransferase

Timepoint

Measurement of serum Alanine Aminotransferase (ALT) levels At the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of curcumin administration

Method of measurement

Blood test

2

Description

Alkaline Phosphatase

Timepoint

Measurement of serum Alkaline Phosphatase (ALP) levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of curcumin administration

Method of measurement

Blood test

3

Description

Aspartate Aminotransferase

Timepoint

Measurement of serum Aspartate Aminotransferase (AST) levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of curcumin

administration
Method of measurement
Blood test

4

Description

Total Bilirubin

Timepoint

Measurement of serum Total Bilirubin levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of curcumin administration

Method of measurement

Blood test

5

Description

Direct Bilirubin

Timepoint

Measurement of serum Direct Bilirubin levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of curcumin administration

Method of measurement

Blood test

6

Description

Ferritin

Timepoint

Measurement of serum ferritin levels at the beginning of the study and 1, 2, 3, 4, 5 and 6 months after initiation of curcumin administration

Method of measurement

Blood test

7

Description

liver T2*MRI

Timepoint

Measurement of liver T2*MRI at the beginning of the study and 6 months after initiation of curcumin administration

Method of measurement

Magnetic Rsonance Imaging

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive 500 mg curcumin tablet (Razak pharmaceutical product) every 12 hours.

Category

Treatment - Drugs

2

Description

Control group: receive placebo pill every 12 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Ali Asghar Children's Hospital

Full name of responsible person

Aziz Eghbali

Street address

Ali Asghar Children's Hospital, Zafar St, Modares Hwy

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eghbali.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abas Motevalian

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Iran University of Medical Sciences, next to Milad Tower, Hemat Hwy

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motevalian.a@iums.ac.ir

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**

Iran University of Medical Sciences

Full name of responsible person

Aziz Eghbali

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

pediatric hematology oncology

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Iran University of Medical Sciences

Full name of responsible person

Aziz Egbali

Position

Associate professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Latest degree

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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

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

Title and more details about the data/document

The main data used in the analysis will be shared.

When the data will become available and for how long

Access date: 6 months after printing the results

To whom data/document is available

Scientific researchers

Under which criteria data/document could be used

It can be used only in scientific research.

From where data/document is obtainable

Email of the research executive

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

1- Introducing research subject and researcher's organizational affiliation 2- Declaration of research objectives 3- Declaration of data usage process 4- Setting up research cooperation memorandum between research executives and applicants of data

Comments