Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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

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Iran (Islamic Republic of)

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+98 21 2268 8027

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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 ح 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
۱۴۴۹۶۱۴۵۳۵
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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
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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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
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