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 at Amirkabir hospital in Arak in 2020.

Protocol summary

Study aim

The effect of oral curcumin on liver enzymes and liver T2 * MRI in patients with thalassemia major and intermediate is determined.

Design

The clinical trial has two intervention and control groups, double-blind, randomized on 60 patients. For randomization, the block method is used using 4 blocks (AABB, ABBA, BABA, etc.).

Settings and conduct

In this study, there are two groups of intervention and control. The intervention group will be given curcumin and the control group will be given a placebo. Both groups receive the same medication for 6 months. The required information will be collected at Amirkabir Hospital in Arak. This study is a double-blind study. Participants will be blinded using the same appearance of curcumin and placebo, and patients have no idea which group they belong to. Also, the researcher who gives the drugs to the two groups will not be aware of the type of drug and the researcher will be blinded in this way.

Participants/Inclusion and exclusion criteria

Age over 5 years old; patients with thalassemia major and intermedia; having conscious satisfaction; no contraindications to the drug under study (curcumin); do not take drugs that affect liver metabolism and liver enzymes and ferritin levels; no liver problems or pregnancy; no history of turmeric allergy.

Intervention groups

Participants in the intervention group will be given curcumin capsules twice a day for 6 months. The control group will be given a placebo. The appearance and dosage of this drug will be similar to curcumin.

Main outcome variables

Liver iron load as a result of this study was investigated that is one of common problems in patients with thalassemia major and intermedia. Initially, the levels of liver enzymes and bilirubin (total and direct) and ferritin will be measured and liver T2 * MRI will be performed for patients and these cases will be compared with the end of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200807048328N1**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Arash Vahdati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0470

Email address

arashvhdt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

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 at Amirkabir hospital in Arak in 2020.

Public title
Effect of Curcumin on Liver enzymes and Liver T2*MRI in patients with Thalassemia.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 5 years old. Patients diagnosed with Thalassemia major and intermedia. Having conscious satisfaction.
Exclusion criteria:
Pregnancy. History of liver disease. Consumption of drugs affecting liver metabolism and liver enzymes and ferritin levels. History of turmeric allergy. Having bleeding disease. Taking anticoagulants.
Age
From **5 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The stochastic method of this study will be block type using 4 blocks (AABB, ABBA, BABA, etc.). For this purpose, the letter Intervention (I) is written on two cards and the letter Control (C) is written on two cards. To hide, the cards are placed in the envelope and turned upside down several times so that the order is not clear. Upon arrival of each participant, a card is selected for him and the selected card is discarded. This is also done for the next three patients to identify 4 people. Then, in the same way, randomization will be done for other groups of 4 to achieve the desired sample size. Then, after randomization and assigning the person to one of the groups, the necessary tests mentioned above are performed for him. The drug is then given to the person for 6 months as mentioned above and every month and after 6 months, tests are performed for him again. In addition, at the beginning of the project, informed written consent and demographic information such as age, sex, height, weight and body mass index will be completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind study. Participants will be blinded using the same appearance of curcumin and placebo, and patients have no idea which group they belong to. Also, the researcher who gives the drugs to the two groups will not be aware of the type of drug and the researcher will be blinded in this way.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Second floor, Research Deputy Building, Complex of Payambare Azam, Basij Square (Sardasht)
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2020-10-05, 1399/07/14
Ethics committee reference number
IR.ARAKMU.REC.1399.203

Health conditions studied

1

Description of health condition studied
Iron Overload in Beta Thalassaemia Major and Intermedia patients
ICD-10 code
D56
ICD-10 code description
Thalassemia

Primary outcomes

1

Description
Aspartate aminotransferase
Timepoint
At the beginning of the study and every month for up to

6 months.

Method of measurement

Patient blood sample.

2

Description

Alanine transaminase

Timepoint

At the beginning of the study and every month for up to 6 months.

Method of measurement

Patient blood sample.

3

Description

Alkaline phosphatase

Timepoint

At the beginning of the study and every month for up to 6 months.

Method of measurement

Patient blood sample.

4

Description

Total bilirubin.

Timepoint

At the beginning of the study and every month for up to 6 months

Method of measurement

Patient blood sample.

5

Description

Direct bilirubin

Timepoint

At the beginning of the study and every month for up to 6 months

Method of measurement

Patient blood sample

6

Description

Serum Ferritin

Timepoint

At the beginning of the study and every month for up to 6 months

Method of measurement

Patient blood sample

7

Description

T2*-weighted imaging

Timepoint

At the beginning of the study and 6 months later

Method of measurement

Magnetic resonanse imaging machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: participants in the intervention group will be given the drug curcumin karen containing 95% turmeric extract. This drug will be given as a capsule in the amount of 500 mg twice a day, daily for 6 months.

Category

Treatment - Drugs

2

Description

Control group: a placebo will be given to participants in the control group. The appearance of this drug will be exactly the same as curcumin (we put it in similar pillboxes) and 2 capsules a day for up to 6 months will be given to patients in this group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Arash Vahdati

Street address

Amirkabir hospital, Parastar Square, Shahid shirudy Ave, Arak Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Kamali

Street address
Vice Chancellor for Research and Technology, Payambar Azam University Complex, Arak University of Medical Sciences, Basij Square (Sardasht)

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Arash Vahdati

Position
Intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Arash Vahdati

Position
Intern

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Arash Vahdati

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

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