

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation the effect of Chicory in decreasing serum Ferritin and liver enzymes in major Thalassemia patients

Protocol summary

Study aim

Evaluation the effect of Chicory in decreasing serum Ferritin and liver enzymes in major Thalassemia patients

Design

The clinical trial is one-sided blind from the analyst's side. We have a control group that is parallel to the intervention group. Phase 3 is a clinical trial conducted on 54 patients. Randomization is done in blocks and with cards. This study is one-sided blind. In this way, the researcher and the patient know about the received treatment and there is no possibility of blinding them, but in order to avoid bias in the analysis, the analyst will not know about the codes of the treatment group to which the patients belong.

Settings and conduct

Patients admitted to the hematology department of Amirkabir Arak Hospital and with the opinion of a hematology specialist who are treatment with Chelator (routine treatment) will be included in the study. This study is one-sided blind from the analyst's side. First, the patient's serum ferritin and liver enzyme levels were measured, then chicory extract was added to the treatment of the intervention group and they received 5 cc every twelve hours, and the control patients only received routine treatment. Again, after three months, the level of liver enzyme and Ferritin of patients of two groups will be measured again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with thalassemia major and Ferritin above 500
Exclusion criteria : allergy and hepatitis

Intervention groups

The intervention group of this study is chicory plant extract with a concentration of 417 mg per 5 cc prepared from the Faculty of Traditional Medicine of Tehran University of Medical Sciences, which is given 5 cc every twelve hours for three months to the intervention group in addition to routine medication. The control group of this study only receives the routine medicine related to

the disease.

Main outcome variables

Ferritin, ALT, AST, ALK

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230704058674N1**

Registration date: **2023-12-21, 1402/09/30**

Registration timing: **prospective**

Last update: **2023-12-21, 1402/09/30**

Update count: **0**

Registration date

2023-12-21, 1402/09/30

Registrant information

Name

mozhgan jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3403 5290

Email address

mozhgaanjafari1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effect of Chicory in decreasing serum Ferritin and liver enzymes in major Thalassemia patients

Public title
Investigating the effect of chicory in the treatment of thalassemia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Consent of patients to participate in the study
 thalassemia major patients treated with periodic pack cell transfusion ferritin>500
Exclusion criteria:
 disinclination to participate or continue studying
 Occurrence of skin complications or other symptoms suggestive of sensitivity to chicory plant extract Viral hepatitis or known liver disease

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: 52

Randomization (investigator's opinion)
Randomized

Randomization description
After the identification of the patient and his permission, he is officially included in the study. The researcher has used the random bock method. In this way, patients with two treatment models c= consumption of chicory sweat p = not consuming chicory And he used the table of random numbers with 6 transformations using the <https://www.sealedenvelope.com> site. The numbers 1 2 3 are specific to treatment c and 4 5 6 are specific to treatment p. Zero is also ignored. For example, using the table of six random transformations: 5 1 4 3 2 6 pccpcp

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single-blind. In this way, the researcher and the patient know about the received treatment and there is no possibility of blinding them, but to avoid bias in the analysis, the analyst will not know about the codes of the treatment group to which the patients belong.

Placebo
Not 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 science

Street address

forth floor,mehr3 bulding, no 5 negin ave, hepco street, arak town

City

arak

Province

Markazi

Postal code

3818989489

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.ARAKMU.REC.1402.076

Health conditions studied

1

Description of health condition studied

Beta Thalassemia major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

ferritin

Timepoint

Initial ferritin measurement (before the start of the intervention), 3 months after consumption of chicory

Method of measurement

Biochemistry blood test

Secondary outcomes

1

Description

liver enzyme

Timepoint

Liver enzyme measurement at the beginning of the study (before consuming chicory) and three months after consuming chicory

Method of measurement

Biochemistry blood test

Intervention groups

1

Description

Intervention group: Chicory herbal extract prepared from Tehran School of Traditional Medicine with a concentration of 417 mg per cc, 5 cc every 12 hours for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Not consuming Chicory

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

dr Mozghan Jafari

Street address

Amirkabir Hospital, Parastar square, Rah ahan street

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mozhgaanjafari1994@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Shaghaiegh Khodaadi

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Sardasht street,

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Medical science of Arak university

Proportion provided by this source

10

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

mozghan jafari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mozghan jafari

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Mozhgan jafari
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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