Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study on oral syrup of extract Cichorium intybus root on decreasing liver enzymes in thalassemia patients in Mohammad Kermanshahi hospital of Kermanshah city.

Protocol summary

Study aim
The effect of oral administration of chicory extract on serum levels of AST and ALT in patients with thalassemia.

Design
Clinical trial with control group, with parallel, blinded and randomized groups

Settings and conduct
Patients are routinely referred for LFT and ferritin measurements every three months. After obtaining written consent from patients, the level of ferritin and liver enzymes will be measured and recorded. Then people with random allocation will be divided into two groups. In the first group (intervention) patients will receive chicory extract as a medicinal supplement. The amount of chicory extract will be evaluated based on the BMI of the patients. Containing 200 mg in 5 ml of chicory extract will be prescribed. In the second group (control) patients will be given a placebo for three months The chicory or placebo extract will be prescribed as a supplement. Liver enzymes levels will be measured at baseline, one and a half months later, three months later, and six months later. Ferritin levels will be measured at baseline, three months, and six months later.

Participants/Inclusion and exclusion criteria
The study population will be patients with thalassemia referred to Dr. Mohammad Kermanshahi Hospital. Entry requirements: AST and ALT impaired Exclusion criteria: high ferritin 2, liver failure or viral hepatitis

Intervention groups
Intervention group: Blood transfusion-dependent thalassemic patients with abnormal liver enzymes are treated with chicory extract for three months and their liver enzymes are evaluated. Control group: Blood transfusion-dependent thalassemia patients with impaired liver enzymes receive placebo in addition to their medications for three months and their liver enzymes are evaluated.

Main outcome variables
Amount of decrease liver enzymes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111001007677N6**
Registration date: **2020-02-13, 1398/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-13, 1398/11/24**
Update count: **0**

Registration date
2020-02-13, 1398/11/24

Registrant information

Name
Mohamadreza Golpayegani
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-20, 1398/10/30

Expected recruitment end date
2020-02-19, 1398/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study on oral syrup of extract Cichorium intybus root on decreasing liver enzymes in thalassemia patients in Mohammad Kermanshahi hospital of Kermanshah city.

Public title
Study on oral syrup of extract Cichorium intybus root on decreasing liver enzymes in thalassemia patients in Mohammad Kermanshahi hospital of Kermanshah city.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
major and intermediate thalassemic pations with abnormal AST and ALT
Exclusion criteria:
liver failure viral hepatitis ferritin level more than 3000
Age
From **2 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization and random assignment of people to two groups is done by generating random numbers using the random number table. That is, the participants in the study were divided into intervention and control groups by simple and individual randomization with the help of random number table. In this method, the person assigned to the first selected number (randomly) is placed in the intervention group and the person assigned to the next selected number (randomly) is assigned to the control group and this process until the end of assignment of people to two groups. Intervention and control continue.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants in the study and the data analyzer are blind for drug or placebo administration. Medication and placebo had the same packaging, taste, volume, and color.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Building No.2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Approval date
2019-12-17, 1398/09/26
Ethics committee reference number
IR.KUMS.REC.1398.895

Health conditions studied

1

Description of health condition studied
thalassemia disease
ICD-10 code
D56
ICD-10 code description
Thalassemia

Primary outcomes

1

Description
Aspartate aminotransferase
Timepoint
At baseline, one and a half months later, three months later, six months later
Method of measurement
ELISA method and iranian science antibody kits

2

Description
Alanin aminotransferase
Timepoint
At baseline, one and a half months later, three months later, six months later
Method of measurement
ELISA method and iranian science antibody kits

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive chicory extract as a medicinal supplement. The amount of chicory extract will be evaluated based on the BMI of the patients. Gram will be administered in 5 ml of chicory extract. The chicory extract is manufactured and standardized by the Razi University School of Pharmacy.
Category
Treatment - Drugs

2

Description
Control group:Patients in the control group will receive placebo at the rate of twenty-eight milligrams per kilogram of body weight. The placebo will be developed and standardized by Razi University School of Pharmacy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Kermanshahi Hospital
Full name of responsible person
Fariba Veisi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kermanshah 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
Kermanshah University of Medical Sciences
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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