Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation the effectiveness and non effectiveness of oral administration of chicory extract on the decrease of ferritin serum in patients with thalassemia major and intermedia

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of oral administration of chicory extract on the decrease of ferritin serum in patients with thalassemia major an intermedia. This study is a single blind clinical trial. The study population will be included patients with thalassemia Major admitted to Mohammad Kermanshahi hospital, a total of 100 patients with thalassemia major will be selected in available method and randomly placed in two intervention and control groups. Patients in the intervention group will receive 200 mg of chicory syrup daily as a supplemental therapy along with iron chelation. In the control group 200 mg placebo will be prescribed in addition to iron chelation. Baseline, two months after the start of treatment and two months after the end of treatment, again ferritin levels will be measured in the laboratory. For measuring ferritin ELISA method and padtan elm manufactured in Iran will be used. Inclusion criteria: Patients with thalassemia major; Patients with serum ferritin between 1000 and 3000. Exclusion criteria: Patients with heart failure, hypertension and diabetes; Patients who have more than 3,000 ferritin in routine check

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112514333N61**
Registration date: **2017-03-05, 1395/12/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-05, 1395/12/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effectiveness and non effectiveness of oral administration of chicory extract on the decrease of ferritin serum in patients with thalassemia major and intermedia

Public title

Study of Chicory per oral administration effect in decreasing serum Ferritin level in major and intermediate beta thalassemia patient.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with thalassemia major; Patients with serum ferritin between 1000 and 3000. Exclusion criteria: Patients with heart failure, hypertension and diabetes; Patients who have more than 3,000 ferritin in routine check

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

kums.rec.1395.662

Health conditions studied

1

Description of health condition studied

Major Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Serum ferritin levels

Timepoint

Baseline, two months after the start of treatment and two months after the end of treatment

Method of measurement

Based on lab

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the intervention group will receive 200 mg of chicory syrup daily as a supplemental therapy along with iron chelation.

Category

Treatment - Drugs

2

Description

In the control group 200 mg placebo will be prescribed in addition to iron chelation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Dr. Farzaneh Roostaei

Street address

Mohammad Kermanshahi Hospital, Crossroads of shirkhorshid

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person
Koroush Hamzehee
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Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty