

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of effects of aqueous extract of Iranian oak (*Quercus brantii*) on antioxidant capacity and stress oxidative of thalassemia patients

Protocol summary

Summary

This study is a double blind clinical trial. Ninety thalassemic patients that refer to Shohada Hospital Lordegan-University of Medical Sciences were selected. All patients have blood transfusion and consume Desferal. Main inclusion criteria for selected Patients are ages of 10-60 years that have regular blood transfusion and chelation intermittent at least four days a week. All Patients under ten years old, hepatitis and HIV positive, heart failure, kidney disease, pregnant women and patients who don't respond to chelation therapy will be excluded. Patients will be divided in to two groups randomly. In this way, patients who complete consent, are identified with numbers. so the patients in each group are selected randomly from among these numbers.. The case group will received daily amount of 300 mg of Oak extract for four months. Control group received placebo for same time. Placebo and Oak extract will prepare in capsule form and classified as A and B code. Blood sample will be collected from patients before and after of study. Aspartate Aminotransferase, Alanine Aminotransferase, Alkaline phosphatase, triglyceride, total cholesterol, HDL-c, glucose, uric acid, bilirubin, Fe, BUN and creatinine, Malone dialdehyde, Ferritin, carbonylated protein, catalase, superoxide dismutase, glutathione peroxidase and total antioxidant capacity of all sample will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040427205N1**

Registration date: **2016-06-27, 1395/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Mahdi Babamir

Name of organization / entity

Shahrekord University of Medical Science

Country

Iran (Islamic Republic of)

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+98 383331671

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Recruitment status

Recruitment complete

Funding source

Shahrekord University Medical Science

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of aqueous extract of Iranian oak (*Quercus brantii*) on antioxidant capacity and stress oxidative of thalassemia patients

Public title

Evaluation of effects of aqueous extract of Iranian oak (*Quercus brantii*) on antioxidant capacity and stress oxidative of thalassemia patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients with thalassemia major 2. patients with regular blood transfusions 3. Patients who received chelation therapy (desferal) at least four days a week 4. 10-60 years old 5. getting informed consent
Exclusion criteria: 1. Under 10 years 2. Positive Hepatitis 3. Positive HIV 4. heart failure and chronic kidney disease 5. pregnancy 6. chelating not answer or other chelating use.

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

During the study, patient groups not aware of the type of intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences.

Street address

Shahrekord University of Medical Science, Rahmatieh, Shahrekord

City

Shahrekod

Postal code

Approval date

2016-03-06, 1394/12/16

Ethics committee reference number

IR.SKUMS.REC.1394.278

Health conditions studied

1

Description of health condition studied

Thalassaemia

ICD-10 code

icd-56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Ferritin

Timepoint

Before and after of study

Method of measurement

ELIZA

2

Description

Iron

Timepoint

Before and after of study

Method of measurement

Biochemical Auto analyzer

3

Description

Glutathione peroxidase

Timepoint

Before and after of study

Method of measurement

Spectrophotometric

4

Description

Catalase

Timepoint

Before and after of study

Method of measurement

Spectrophotometric

5

Description

Superoxide dismutase

Timepoint

Before and after of study

Method of measurement

Spectrophotometric

6

Description

carbonyl protein

Timepoint

Before and after of study

Method of measurement

Spectrophotometric

7

Description

Malondialdehyde

Timepoint

Before and after of study

Method of measurement

HPLC

8

Description

Total Capacity Antioxidant

Timepoint

Before and after of study

Method of measurement

Spectrophotometric

Secondary outcomes

1

Description

Alanin Transferase

Timepoint

Before and after of study

Method of measurement

Biochemical auto analyzer

2

Description

Aspartate amino transferase

Timepoint

Before and after of study

Method of measurement

Biochemical auto analyzer

3

Description

Triglyceride

Timepoint

Before and after of study

Method of measurement

Biochemical auto analyzer

4

Description

Cholestrol

Timepoint

Before and after of study

Method of measurement

Biochemical auto analyzer

Intervention groups

1

Description

Intervention group : Patients with thalassemia major will receive two capsules daily for four months each capsule

contains 150 mg extract oak

Category

Treatment - Drugs

2

Description

Control group: thalassemia Patients in the control group will receive two placebo capsule daily for four months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lordegan Shohada Hospital

Full name of responsible person

Vice chancellor for research, Shahrekord University of Medical Sciences

Street address

Kashani Street ; Shahrekord, Shahrekord University of Medical Sciences

City

Sharekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sharekord University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Sharekord University of Medical Sciences

Street address

Kashani Blvd:, Kashani St:, Shahrekord, Vice chancellor for research, Shahrekord university of medical science

City

Shrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sharekord 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

Contact

Name of organization / entity

Sharekord University of Medical Science

Full name of responsible person

Mahdi Babamir

Position

MSc

Other areas of specialty/work**Street address**

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Fax

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