

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Study of the synergistic effects of grape seed extract with deferasirox on oxidative stress, hemoglobin levels, blood coagulation, serum ferritin levels and inflammatory biomarkers in children with major thalassemia

#### Protocol summary

##### Study aim

Study of the synergistic effects of grape seed extract with deferasirox on oxidative stress, hemoglobin levels, blood coagulation, serum ferritin levels and inflammatory biomarkers in children with major thalassemia

##### Design

A randomized, blinded, controlled clinical trial of 60 patients, enrolled between August 2020 and March 2021, and followed for 2 months

##### Settings and conduct

A randomized, blinded controlled clinical trial of 60 children with thalassemia major who meets inclusion criteria without any of the exclusion criteria are enrolled in the study. The study is performed in hematology and oncology Specialty and sub-specialty shahid Baghaee 2 hospital. Patients are randomly stratified into 2 groups. The first group receives deferasirox 30 mg/Kg PO daily and the second group receives deferasirox 30 mg/Kg PO daily plus grape seed extract 100 mg PO daily. patients and major researcher are blinded via simulation of drug and placebo packages. Data is collected at the start of the study, after 2 weeks and 4 weeks of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients affected by major thalassemia; Iron chelators consumption for at least 2 years; A history of iron chelators steady dose for the last 3 months; Having serum ferritin level more than 1000 µg/L  
Exclusion criteria: Change in iron chelator therapy during the study (6 months)

##### Intervention groups

Control group receives deferasirox 30mg /Kg daily PO.  
Case group receives deferasirox 30 mg/Kg daily plus grape seed extract 100 mg daily PO.

##### Main outcome variables

Glutathione peroxidase, superoxide dismutase, malondialdehyde, Glutathione, Hemoglobin, red blood cell count, prothrombin time, partial thromboplastin

time,international normalized ratio, Billirubin direct and indirect, aminotransferase enzymes, alkaline phosphatase, Ferritin level, catalase enzyme activity, tissue necrosis factor-α, serum Albumin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180603039959N2**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

##### Registration date

2020-10-05, 1399/07/14

##### Registrant information

##### Name

bijan keikhaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3375 0410

##### Email address

keikhaeib@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Study of the synergistic effects of grape seed extract with deferasirox on oxidative stress, hemoglobin levels, blood coagulation, serum ferritin levels and inflammatory biomarkers in children with major thalassemia

**Public title**  
Effects of grape seed extract on thalassemia major

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients affected by major thalassemia Iron chelators consumption for at least 2 years A history of iron chelator steady dose for the last 3 months Having serum ferritin level more than 1000 µg/L Patients with age limitation of 2 to 18 years old

**Exclusion criteria:**

Change in iron chelator therapy during the study (6 months)

**Age**

From **2 years** old to **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is simple. Randomization unit is individual. Randomization tool is sealed envelope. Concealment is performed through similar capsules containing drug and placebo. Random sequence generation is made by envelopes shuffling.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double blind study, participants and the major researcher are kept blind to the study groups. Randomization tool is sealed envelope so that the major researcher is unaware of the envelope content delivered to the patients. Concealment is performed through similar capsules containing drug and placebo so that the participants are unaware of the prescribed drug .

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Golestan Ave., Shahid Baghaee sq., Shahid Baghaee 2 hospital.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6138933333

**Approval date**

2020-06-29, 1399/04/09

**Ethics committee reference number**

IR.AJUMS.REC.1399.307

## Health conditions studied

### 1

**Description of health condition studied**

Thalassemia major

**ICD-10 code**

D56.1

**ICD-10 code description**

Beta thalassemia

## Primary outcomes

### 1

**Description**

Glutathion peroxidase enzyme activity

**Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

**Method of measurement**

For measurement of glutathion peroxidase enzyme activity ZellBio kits are used.

### 2

**Description**

Superoxide dismutase enzyme activity

**Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

**Method of measurement**

For measurement of Superoxide dismutase enzyme activity ZellBio kits are used.

### 3

#### **Description**

Catalase enzyme activity

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

For measurement of Catalase enzyme activity ZellBio kits are used.

### 4

#### **Description**

TNF-alpha level

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

For measurement of TNF-alpha level IBL kit is used.

### 5

#### **Description**

Malon dyaldehyde level

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

For measurement of malon dyaldehyde the Satho method is used.

### 6

#### **Description**

Hemoglobin level

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Hemoglobin level is measured by Complete blood count test.

### 7

#### **Description**

Red blood cell count

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Red blood cell count is measured by Complete blood count test.

### 8

#### **Description**

Serum ferritin level

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Serum ferritin level is measured by serum ferritin level.

### 9

#### **Description**

Serum aminotransferase

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Serum aminotransferase is measured by aspartate aminotransferase (AST) test and alanine aminotransferase (ALT) test.

### 10

#### **Description**

Blood urea nitrogen level

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Serum blood urea nitrogen level is measured by Blood urea nitrogen (BUN) test.

### 11

#### **Description**

Serum creatinine

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Serum creatinine level is measured by creatinine test.

### 12

#### **Description**

Prothrombin time

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Prothrombin time is measured by Prothrombin time (PT) test.

### 13

#### **Description**

Partial thromboplastin time

#### **Timepoint**

At the beginning of the study, after 2 weeks of treatment, after 4 weeks of treatment.

#### **Method of measurement**

Partial thromboplastin time is measured by Partial thromboplastin time (PTT) test.

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### Description

Intervention group: Patients are treated for 4 weeks with grape seed extract (made in Shari Pharmaceutical Industrial Company) 100 mg PO daily in combination with Deferasirox (made in Exir Pharmaceutical Industrial Company) 30 mg/Kg PO daily.

### Category

Treatment - Other

## 2

### Description

Control group: Patients are treated for 4 weeks with Deferasirox (made in Exir Pharmaceutical Industrial Company) 30 mg/Kg PO daily.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Baghaee 2 hospital

##### Full name of responsible person

Bijan Keikhaei dehdezi

##### Street address

Golestan Ave., Shahid Baghaee sq., Shahid Bagjhee 2 hospitl.2

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6138933333

##### Phone

+98 61 3375 0411

##### Email

keikhaeib@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Bijan Keikhaei dehdezi

##### Street address

Golestan Ave., Shahid Baghaee sq., Shahid Baghaee 2 hospital.

##### City

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##### Province

Khouzestan

##### Postal code

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##### Phone

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##### Email

keikhaeib@yahoo.com

##### Grant name

Vice Chancellor for Research, Ahvaz University of Medical Sciences

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Bijan Keikhaei dehdezi

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Medical Education

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golestan Ave., Shahid Baghaee sq., Shahid Baghaee 2 hospital

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6138933333

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00980166173271

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keikhaeib@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Bijan Keikhaei dehdezi

##### Position

Professor

##### Latest degree

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Bijan Keikhaei dehdezi

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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**

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**

Not applicable

**Data Dictionary**

Not applicable