Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 envelops 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

Khouzestan

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
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Golestan Ave., Shahid Baghaee sq., Shahid Bagjhee 2 hospitl.2
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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Email
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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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Person responsible for updating data

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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