

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Evaluation of the effects of alpha lipoic acid or placebo on lipid profile, oxidative stress and iron overload in patients with β -thalassemia major.

Protocol summary

Study aim

Evaluation the effects of alpha lipoic acid on lipid profile, oxidative stress and iron overload in patients with β -thalassemia major.

Design

Clinical trials with control group, crossover, double-blinded, randomized

Settings and conduct

In this double-blind clinical trial, patients with β -thalassemia major who are referred to Mohammad Kermanshahi Hospital are selected according to inclusion criteria and approved by the physician.

Participants/Inclusion and exclusion criteria

Inclusion criteria include ages over 15 years old and exit criteria including the history of hepatitis B and C, heart failure and renal failure, cancer, allergies, drug-induced disordered digestive problems, pregnancy, smoking, The use of shlaturi except desphonac and following a particular diet.

Intervention groups

At the beginning of the intervention, half of the patients will receive the alpha-lipoic acid (supplement group) and patients will be asked to take a 600 mg capsule of alpha-lipoic acid for 8 weeks each day in addition to their chelator. The other half of the patients take placebo which is apparently similar to the alpha-lipoic acid (the placebo group), these patients also receive a placebo for 8 weeks in addition to their chelator. In order to eliminate the complementary and placebo interaction, the duration of washout is considered for 3 weeks, and when it passes, the next stage of the clinical trial will begin with a crossover. In the second intervention period, the two groups will be displaced.

Main outcome variables

Total antioxidant capacity, Malondialdehyde, Serum Iron, Ferritin, Transferrin, homocysteine (HCY), Lipoprotein-associated phospholipase A2 (Lp-PLA2), Trimethylamine N-oxide (TMAO), Osteoprotegerin (OPG)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061714237N2**

Registration date: **2017-08-15, 1396/05/24**

Registration timing: **prospective**

Last update: **2018-07-05, 1397/04/14**

Update count: **1**

Registration date

2017-08-15, 1396/05/24

Registrant information

Name

Elham Sharifi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1730 6006

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effects of alpha lipoic acid or placebo on lipid profile, oxidative stress and iron overload in patients with β -thalassemia major.

Public title
Effects of alpha lipoic acid on β - Thalassemia Major

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 15 years
Exclusion criteria:
History of hepatitis B and C heart failure and kidney failure cancer allergies digestive problems disrupting drug intake pregnancy smoking The use of shlaturi except Desphonac following a particular diet

Age
From **15 years** old to **30 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using randomized block design method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, none of the subjects and researchers do not know who is in what group.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences
Street address
Shahid Beheshti Blvd- Kermanshah
City
Kermanshah

Province
Kermanshah
Postal code
0
Approval date
2017-06-14, 1396/03/24
Ethics committee reference number
KUMS.REC.1396.144

Health conditions studied

1

Description of health condition studied
 β -thalassemia Major
ICD-10 code
D56.1
ICD-10 code description
Beta thalassaemia

Primary outcomes

1

Description
Total antioxidant capacity
Timepoint
Week 0, Week 8, Week 11, Week 19
Method of measurement
nmol/ml, ELIZA

2

Description
Malondialdehyde
Timepoint
Week 0, Week 8, Week 11, Week 19
Method of measurement
nm/ml, Tiobarbitoric acid

3

Description
Serum Iron
Timepoint
Week 0, Week 8, Week 11, Week 19
Method of measurement
 μ mol/ml, photometric

4

Description
Ferritin
Timepoint
Week 0, Week 8, Week 11, Week 19
Method of measurement
ngram/ml, ELIAZ

5

Description
Transferrin

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

µgram/ml, ELIZA

6

Description

homocysteine (HCY)

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

µmol/L, ELIZA

7

Description

Lipoprotein-associated phospholipase A2 (Lp-PLA2)

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

nmol/mL, ELIZA

8

Description

Trimethylamine N-oxide (TMAO)

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

µmol/L, ELIZA

9

Description

Osteoprotegerin (OPG)

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

mg/dl, ELIZA

Secondary outcomes

1

Description

Serum Triacylglyceride

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

mg/dl, Enzymatic

2

Description

Serum Cholesterol

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

mg/dl, Enzymatic

3

Description

HDL-c

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

mg/dl, Direct Enzymatic

4

Description

LDL-c

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

mg/dl, FriedWald Formula

5

Description

Body Weight

Timepoint

Week 0, Week 8, Week 11, Week 19

Method of measurement

Scale, Kilogram

Intervention groups

1

Description

Intervention group: 600 mg alpha lipoic acid (C8H14O2S2) capsules once a day for 8 weeks. Product of Support Nutrition company, USA.

Category

Treatment - Other

2

Description

Control group: 600 mg placebo capsules (corn flour) similar to alpha lipoic acid in shape and color once a day for 8 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Elham Sharifi Zahabi

Street address

Mohammad Kermanshahi Hospital, Mosavari Avenue, Kermanshah

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khadijeh.jamshidi93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Behrooz Hamzeh
Street address
Deputy of Research and Technology- Kermanshah
University Of Medical Sciences- Shahid Beheshti Blvd.
City
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Postal code
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+98 83 1725 7696
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kbehrooz.hamzeh@kums.ac.ir

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
Full name of responsible person
Hadi Abdollahzad
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address

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Person responsible for updating data

Contact

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Full name of responsible person
Elham Sharifi Zahabi
Position
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Latest degree
Master
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is unobtrusive when unrecognizable

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

All people have permission to access

Under which criteria data/document could be used

In case of confidentiality of data

From where data/document is obtainable

hadi_nut@yahoo.com

What processes are involved for a request to access data/document

By submitting a request to the researcher, the relevant request will be reviewed.

Comments