Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Email address
elham_sharifi@nutr.mui.ac.ir

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
µmol/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 ($C_8H_{14}O_2S_2$) 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
City
Kermanshah
Province
Kermanshah

Postal code
0
Phone
+98 83 3721 8204
Email
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
Kermanshah
Province
Kermanshah
Postal code
0
Phone
+98 83 1725 7696
Email
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
School of Nutrition and Food Sciences-Next to the Farabi hospital- Isar Square-Kermanshah
City
School of Nutrition and Food Sciences-Next to the Farabi hospital- Isar Squre-Kermanshah
Province
Kermanshah
Postal code
0
Phone
+98 83 3826 2052
Fax
Email
Hadi_Nut@yahoo.com
Web page address

Person responsible for scientific 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
School of Nutrtion and Food Sciences- Next to Farabi Hospital- Isar Square-Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
0
Phone
+98 83 3826 2052
Fax
Email
hadi_nut@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Imam khomeini Comprehensive Health center
Full name of responsible person
Elham Sharifi Zahabi
Position
MSc
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Imam khomeini Town- Kermanshah
City

Kermanshah

Province

Kermanshah

Postal code

Iran

Phone

00

Fax

Email

elham_sharifi@nutr.mui.ac.ir

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