

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the efficacy of N-Acetylcysteine and vitamin E supplementation on oxidative stress status in patients with transfusion-dependent β -thalassemia

Protocol summary

Study aim

Efficacy and safety of N-Acetylcysteine and vitamin E supplementation on oxidative stress status in patients with transfusion-dependent β -thalassemia

Design

In this open-label randomized controlled trial (phase 3), 75 patients with transfusion-dependent & beta - thalassemia will be enrolled. Patients will be randomly allocated in three groups by block randomization method (n=25 in each group).

Settings and conduct

Thalassemia clinic of Dastgheib hospital affiliated to Shiraz University of Medical Sciences. Duration of study is three months. At baseline and at the end of the study, patients will be checked for primary and secondary endpoints

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with transfusion-dependent beta-thalassemia above 18 years old Treating by at least one or combination of iron chelation therapy agents
Exclusion criteria: No desire to participate in the study
Being positive for hepatitis B, C or HIV
Pregnancy
Presentation of an acute infectious disease
Narcotic addiction
Under treatment with nitroglycerine or other related drugs
Asthma
Known allergy to NAC

Intervention groups

First group NAC group, the second group is the vitamin E group, and the third group is the control group receiving no treatment.

Main outcome variables

Serum TOS and TAC levels at baseline and at the end of the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081207001494N3**

Registration date: **2019-07-02, 1398/04/11**

Registration timing: **prospective**

Last update: **2019-07-02, 1398/04/11**

Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

sezaneh haghpanah

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 2263

Email address

haghpanah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of N-Acetylcysteine and

vitamin E supplementation on oxidative stress status in patients with transfusion-dependent β -thalassemia

Public title

N-acetylcysteine and vitamin E in transfusion dependent β -thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with transfusion-dependent beta-thalassemia above 18 years old who were diagnosed by clinical history, and hemoglobin electrophoresis. Receiving regular blood transfusion (15 cc/kg body weight with interval of 3-4 weeks to maintain hemoglobin levels above 9.5 g/dl) Treating by at least one or combination of iron chelation therapy agents including deferasirox (DFX), deferiprone (DFP), and deferoxamine (DFO).

Exclusion criteria:

No desire to participate in the study Being positive for hepatitis B, C or HIV Pregnancy Presentation of any acute infectious disease Narcotic addiction Under treatment with nitroglycerine or other related drugs Asthma Known allergy to NAC

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated in three groups by permuted block randomization method (25 permuted blocks, n=3 in each block).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee in Biomedical research

Street address

13th floor, Block A, Central building of Ministry of

Health and Education,-Simay Iran Ave, between South Falamak and Zarafshan, Sharak Ghods (Gharb), Tehran,

City

Shiraz

Province

Fars

Postal code

Approval date

2019-06-11, 1398/03/21

Ethics committee reference number

IR.SUMS.REC.1398.457

Health conditions studied

1

Description of health condition studied

Transfusion dependent beta-thalassemia

ICD-10 code

D56.1

ICD-10 code description

Transfusion dependent beta-thalassemia

Primary outcomes

1

Description

Serum total oxidant status (TOS)

Timepoint

At baseline and at the end of the study

Method of measurement

Blood sampling and using specific kit

2

Description

Total antioxidant capacity (TAC)

Timepoint

At baseline and at the end of the study

Method of measurement

Blood sampling and using specific kit

3

Description

Hemoglobin levels

Timepoint

At baseline and at the end of the study

Method of measurement

Blood sampling

4

Description

Serum ferritin levels

Timepoint

At the beginning of the study and after three months

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Drug adverse events

Timepoint

Monthly

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: The N-Acethyl Cystein Group

Category

Treatment - Drugs

2

Description

Intervention group: .The vitamin E group

Category

Treatment - Drugs

3

Description

Control group: No treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Thalassemia Clinic of Dastgheib Hospital

Full name of responsible person

Omidreza Zekavat

Street address

Shahid ayatollah Dastgheib, Beside National Garden,
Hafez street, Shiraz

City

Shiraz

Province

Fars

Postal code

3769-71456

Phone

+98 71 3228 8064

Fax

Email

Dastgheib@sums.ac.ir

Web page address

<http://dastgheib.sums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Unes Ghasemi

Street address

Shiraz University of Medical Sciences, Zand Ave,
Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sezaneh Haghpanah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

Hematology research Center, 6th floor, Mohammad
Rasool allah Tower, Namazee hospital, Khalili Ave,
shiraz

City

Shiraz

Province

Fars

Postal code
7193635899
Phone
+98 71 3612 2263
Email
haghpanah@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Omid Reza Zekavat
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology Oncology
Street address
Hematology research Center, 6th floor, Mohammad Rasool allah Tower, Namazee hospital, Khalili Ave, shiraz
City
Shiraz
Province
Fars
Postal code
7193635899
Phone
+98 71 3612 2265
Email
ozekavat@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Sezaneh Haghpanah
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Hematology research Center, 6th floor, Mohammad Rasool allah Tower, Namazee hospital, Khalili Ave, shiraz
City
Shiraz
Province
Fars
Postal code
7193635899
Phone
+98 71 3612 2263
Email
haghpanah@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Possibility of preparing another supplementary project

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available