

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effect of vitamin E on prevention of acute kidney injury and Fanconi syndrome caused by iron chelators in thalassemia patients

Protocol summary

Study aim

Determining the frequency of Acute Kidney Injury in the intervention group
Determining the frequency of Acute Kidney Injury in the control group
Determining the frequency of Fanconi syndrome in the intervention group
Determining the frequency of Fanconi syndrome in control group patients
Comparison of renal function in the intervention group with the control group

Design

A clinical trial with intervention and control groups, unblinded, randomized, phase 3 on 50 patients. The randomization function of Excel software was used for randomization.

Settings and conduct

All patients with thalassemia major who Amirkabir Hospital covers are included in the study after signing the informed consent. Then we randomly divided 50 patients into 2 intervention and control groups. The intervention group, in addition to the standard treatment, use iron chelator (nanojade), and vitamin E with a dose of 400 milliunits, and the control group only the standard treatment. 48 hours and 7 days after the beginning of the study, cr, and gfr will be checked in the blood test at the thalassemia department of Amirkabir Hospital, and 30 days after the beginning of the study, VBG, BUN/Cr, U/A, FBS, and serum P will be checked in the blood test And the urine is checked. After collecting information, 2 groups are compared and the effect of vitamin E is checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with thalassemia covered by Amir Kabir Hospital
Non-entry criteria: Those who do not cooperate to enter the study

Intervention groups

Intervention group: patients with thalassemia who receive vitamin E and iron chelators. Control group: patients with thalassemia who do not receive vitamin E but receive iron chelators.

Main outcome variables

creatinine level; glomerular filtration rate; phosphorus

level; urine glucose level; venous blood gas level; ratio of blood urea nitrogen to creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221111056466N1**

Registration date: **2022-12-19, 1401/09/28**

Registration timing: **prospective**

Last update: **2022-12-19, 1401/09/28**

Update count: **0**

Registration date

2022-12-19, 1401/09/28

Registrant information

Name

Mahdi Moradigoudarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4230 8306

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin E on prevention of acute kidney injury and Fanconi syndrome caused by iron chelators in thalassemia patients

Public title

"Effect of vitamin E in preventing kidney problems in thalassemia patients"

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with thalassemia are covered by Amir Kabir Arak Hospital

Exclusion criteria:

All patients who are covered by Amirkabir Hospital but do not consent to participate in the study.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization Each patient in the desired community has an equal chance of being selected Randomization Unit: Individual Randomization tools: Excel Microsoft

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In the intervention group, people receive vitamin E daily for one month, and in the control group, they receive the standard treatment before entering the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Alam-ol-Hoda st, Shahid Shiridi st

City

arak

Province

Markazi

Postal code

3819693345

Approval date

2022-07-31, 1401/05/09

Ethics committee reference number

IR.ARAKMU.REC.1401.133

Health conditions studied

1

Description of health condition studied

Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

2

Description of health condition studied

Acute Kidney Injury

ICD-10 code

N17.0

ICD-10 code description

Acute kidney failure with tubular necrosis

3

Description of health condition studied

Fanconi syndrome

ICD-10 code

E72.0

ICD-10 code description

Disorders of amino-acid transport

4

Description of health condition studied

Abnormal Kidney function

ICD-10 code

R94.4

ICD-10 code description

Abnormal results of kidney function studies

Primary outcomes

1

Description

Creatinine level

Timepoint

It will be checked on the first day of the study and 48 hours and 7 days after the start of the study

Method of measurement

blood samples

2

Description

glomerular filtration rate

Timepoint

It will be checked on the first day of the study and 48 hours and 7 days after the start of the study

Method of measurement

blood sample

3

Description

Blood phosphorus level

Timepoint

It is checked on the first day of the study and 30 days after the start of the study

Method of measurement

blood sample

4

Description

Urine glucose level

Timepoint

It is checked on the first day of the study and 30 days after the start of the study

Method of measurement

urine sample

5

Description

Venous blood gas level

Timepoint

It is checked on the first day of the study and 30 days after the start of the study

Method of measurement

blood sample

6

Description

The ratio of blood urea nitrogen to creatinine

Timepoint

It is checked on the first day of the study and 30 days after the start of the study

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the standard treatment, this group receives a daily iron chelator called Jedneo 360 mg tablet with the generic name Deferasirox of Swiss company NOVARTIS, and vitamin E with a dose

of 400 mg of E-Vigel 400mg Softgel of Iran's Dana Pharmaceutical Company. Deferasirox It leads to an increase in the excretion of iron through feces.

Deferasirox is prescribed in cases where the amount of iron in the body is chronically accumulated due to blood transfusion or diseases such as thalassemia to eliminate excess iron.

Category

Treatment - Drugs

2

Description

Control group: This standard treatment group receives a daily intake of an iron chelator called Jadenio 360 mg tablet with the generic name Deferasirox by Novartis Switzerland. Deferasirox leads to an increase in the excretion of iron through feces. Deferasirox is prescribed in cases where the amount of iron in the body is chronically accumulated due to blood transfusions or diseases such as thalassemia to eliminate excess iron.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Mahdi Moradigoudarzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Parsa Yousefichaijan

Street address

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Mahdi Moradigoudarzi
Position
Student Research Committee
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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 tests taken including cr, gfr, p, fbs, bun/cr, vbg, u/a

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

For all people related to medicine, pharmacy, and laboratory sciences

Under which criteria data/document could be used

no limitation

From where data/document is obtainable

Mahdic moradigoudarzi moradi_goudarzi@yahoo.com

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

Please, after introducing yourself and the field you are working in, ask for the documentation of this project so that it will be sent to him/her a week later.

Comments