Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Evaluation of the effect of vitamin E on prevention of acute kidney injuray 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 rand 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 injuray 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 Defrasirox 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
Street address
Amirkabir Hospital, Parastar Square, Alam-ol-Hoda St
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3819693181
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amirkabir-hospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Parsa Yousefichaijan
Street address
Alam-ol-Hoda St, Shahid Shirodi
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3819693345

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info@arakmu.ac.ir

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
General Practitioner

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No 12, Namavaran 9 Alley, Sepehr St, Andisheh Quarter

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mahdi Moradigoudarzi

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Person responsible for updating data

Contact

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Arak University of Medical Sciences

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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