Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effect of vitamin E on the prevention of acute renal injury in patients with leukemia receiving vincristine

Protocol summary

Study aim
The effect of vitamin E (E) in the prevention of acute kidney injury in leukemia patients receiving vincristine is investigated.

Design
Clinical trial with control group, with parallel group, without blinding, randomized, phase 3 on 36 patients, block randomization method with 4 blocks was used for randomization.

Settings and conduct
It is a randomized clinical trial study with a control group that will be conducted in 1402 at Amirkabir Hospital in Arak city on 36 patients with leukemia treated with vincristine. In this study, after randomization, 18 patients in the control group will receive only routine treatment with vincristine. Meanwhile, 18 patients in the intervention group take 400 units of vitamin E orally daily in addition to routine treatment with vincristine for one month. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 3 to 18 years, - leukemia patients taking vincristine. Exclusion criteria: suffering from chronic kidney disease, allergy to vitamin E medicine

Intervention groups
In the control group, 18 patients will only receive routine treatment with vincristine for one month and will not receive any similar drug with vitamin E. In the intervention group, 18 patients, in addition to routine treatment with vincristine, will receive one vitamin E gelatin capsule, 400 units (Dana Pharmaceuticals-Iran) for one month.

Main outcome variables
Glomerular filtration rate (GFR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044255N7**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date
2023-02-25, 1401/12/06

Registrant information

Name
Ali Azizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-25, 1402/01/05

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vitamin E on the prevention of acute renal injury in patients with leukemia receiving vincristine

Public title
effect of vitamin E on the prevention of acute renal injury

in patients with leukemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Leukemia patients taking vincristine Age 3 to 18 years

Exclusion criteria:

Suffering from chronic kidney disease Allergy to vitamin E medicine

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are placed in one of the intervention and control groups by random block allocation method with blocks of four. By assigning the letter A to the intervention group and the letter B to the control group, six states AABB, BBAA, BABA, ABBA, BAAB and ABAB are written on separate sheets and thrown into a container and randomly one of the sheets is taken out of the container and the composition written on it is noted and that sheet is thrown into the container again. Because the sample size in this study is 36 patients, this procedure is repeated 9 times and each time the combination written on each sheet is noted in the sequence of the order written on the previous sheet. Then, a number from 1 to 36 is assigned to each of the letters in the order of the letters noted one after the other, and each of the letters is placed in an envelope and the number of that letter is written on the envelope. Every time a disease is selected, one of the envelopes is opened according to the number written on the envelope and it is determined that the patient should be in the intervention or control group.

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

Ethics committee of Arak University of Medical Sciences

Street address

Payambar azam complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.ARAKMU.REC.1401.200

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukemia

Primary outcomes

1

Description

Glomerular filtration rate (GFR)

Timepoint

At entry into the study, 48 hours later, one week and one month after the start of treatment

Method of measurement

Creatinine clearance formula

Secondary outcomes

1

Description

Serum creatinine level

Timepoint

At entry into the study, 48 hours later, one week and one month after the start of treatment

Method of measurement

Laboratory measurement of serum creatinine level

Intervention groups

1

Description

Control group: In the control group, 18 patients received routine treatment with vincristine (Richter-Hungary) every week intravenously at a dose of 0.05 mg/kg for one month. During this period, patients will not receive any supplemental medicine containing vitamin E. Also, placebo medicine will not be used in this group.

Category
Treatment - Drugs

2

Description
Intervention group: In the intervention group, 18 patients with leukemia receive routine treatment with vincristine (Richter-Hungary) intravenously at a dose of 0.05 mg/kg every week. In addition, patients in the intervention group will receive one oral gelatin capsule of vitamin E, four hundred units (400 IU) (Dana Pharmaceuticals-Iran) for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir hospital
Full name of responsible person
Alireza Toghra
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Amirkabir hospital, Parastar sq., Shahid Shiroudi st.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Alireza Toghra
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available