

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of vitamin E therapy on children with acute kidney injury

Protocol summary

Study aim

The effect of vitamin E in the treatment of children with acute kidney injury is investigated.

Design

The clinical trial has a control and intervention group without blinding, randomized, phase 2 on 96 patients. the block randomization method was used.

Settings and conduct

In this clinical trial, patients with acute kidney failure referring to Amirkabir Arak Hospital are randomly divided into two intervention and control groups. Both groups are under routine AKI treatment. In the intervention group, in addition to routine treatment, they will receive vitamin E supplement drops daily for ten days. while the control group receives only routine treatment. For both intervention and control groups, creatinine and GFR will be checked upon entering the study, 48 hours later, when they are discharged. The obtained results are recorded in the checklist prepared for this purpose.

Participants/Inclusion and exclusion criteria

1. People with acute kidney failure between the ages of 1 and 13 admitted to Amirkabir Hospital 2. Have the necessary cooperation in following up the treatment 3. Completing the informed consent form. Exit conditions: 1. Intolerance of vitamin E consumption in the intervention group 2. Unwillingness to continue participating in the study

Intervention groups

In the intervention group of patients, in addition to the routine treatment with fluid therapy, daily according to age, according to the following order (the standard daily consumption amount according to the drug brochure) of vitamin E drops from "Behsa" company, each milliliter of which contains 10 international units of vitamin E. will receive for 10 days.

Main outcome variables

Assessment of acute kidney injury with baseline serum creatinine level is done at the beginning of the study, 48 hours later and at the time of discharge.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231119060103N1**

Registration date: **2023-11-24, 1402/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-24, 1402/09/03**

Update count: **0**

Registration date

2023-11-24, 1402/09/03

Registrant information

Name

Roya Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3383 8309

Email address

royaaasadi9877@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-12, 1402/08/21

Expected recruitment end date

2024-07-11, 1403/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin E therapy on children with acute kidney injury

Public title
Evaluation of the effect of vitamin E therapy on children with acute kidney injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 1. People with acute kidney injury between the ages of 1 and 13 admitted to Amirkabir Hospital 2. Have the necessary cooperation in following up the treatment 3. Completing the informed consent form.
Exclusion criteria:
 People who do not want to participate in the study

Age
From **1 year** old to **13 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be done, for this purpose, the participants will be assigned to two intervention and control groups according to the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. . Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

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
 Sardasht St., Salamat St., Arak Medical Sciences Dormitory
City
 Arak
Province
 Markazi
Postal code
 6861748149
Approval date
 2023-09-30, 1402/07/08
Ethics committee reference number
 IR.ARAKMU.REC.1402.165

2

Ethics committee
Name of ethics committee
 Ethics committee of Arak University of Medical Sciences
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Health conditions studied

1

Description of health condition studied
 Acute kidney injury
ICD-10 code
 N17.9
ICD-10 code description
 Acute kidney failure, unspecified

Primary outcomes

1

Description
 The assessment of acute kidney injury is done by measuring the serum creatinine level
Timepoint
 Measurement of serum creatinine level at the beginning of the study, 48 hours later and at the time of discharge
Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

intervention group In addition to the routine treatment with fluid therapy, patients are given vitamin E drops from the "Behsa" company, each milliliter of which contains 10 international units of vitamin E, for 10 day will receive. Age 1-3 years: 18 drops of the desired drug, which is equivalent to 0.9 ml. Age 4-8 years: 21 drops of the desired drug, which is equivalent to 1.05 ml. Age 9-13 years: 33 drops of the desired drug, which is equivalent to 1.65 It is milliliters

Category

Treatment - Drugs

2

Description

Control group: The control group will receive only routine treatment which includes fluid therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr. Ali Arjmand

Street address

Shahid Shiroudi St. - Nurse Square - Amirkabir Hospital

City

Arak

Province

Markazi

Postal code

3819693181

Phone

+98 86 3313 4715

Email

amirkabir-hospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Street address

Arak University of medical science, Basij square

City

Arak

Province

Markazi

Postal code

8735610954

Phone

+98 86 3417 3532

Email

www.salehi58@gmail.com

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

Dr. Ali Arjmand

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Shahid Shiroudi St. - Nurse Square - Amirkabir Arak Hospital

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Postal code

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Phone

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Email

Aliarjmand1@yahoo.com

Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

Contact

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions, as well as people working in the industry, can apply for them

Under which criteria data/document could be used

There are no other conditions

From where data/document is obtainable

To the main person responsible for the study; Dr. Ali Arjmand can be contacted at Aliarjmand1@yahoo.com

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

The applicant can contact the person in charge of the study through the email address and get access to the information as soon as possible after the request

Comments