

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the effect of vitamin E in the prevention of acute renal failure in infants weighing more than 1000 admitted to the neonatal intensive care unit

Protocol summary

Study aim

Evaluation of the effect of vitamin E in the prevention of acute renal failure in infants weighing more than 1000 admitted to the neonatal intensive care unit in Arak Talghani Hospital

Design

The clinical trial is in phase 3 with control group and random allocation in two groups, with parallel groups, double blind strains on 150 patients. For randomization, the easy randomization method will be used using the beads inside the envelope.

Settings and conduct

This study will be conducted as a clinical trial in the neonatal intensive care unit at Amirkabir and Taleghani Hospital in Arak, and the study will be conducted in a double-blind manner in which caregivers and companions are blinded to the study. Infants who are hospitalized in the intensive care unit and do not have contraindications to vitamin E intake will be considered as the study group. In this study, 150 infants who meet the inclusion criteria will be selected. Patients will be randomly assigned into two groups, 75 infants will be in the vitamin E group and 75 children will be in the control group. The treatment continued for 6 days and the creatinine level was recorded before and after the treatment.

Participants/Inclusion and exclusion criteria

Infants hospitalized in the neonatal intensive care unit weighing more than 1000 grams and not having any congenital or chromosomal abnormalities are considered as the study group, and infants with vitamin E sensitivity, any contraindications to vitamin E consumption, and lack of consent to participate in the study will be excluded from the study.

Intervention groups

In the intervention group, vitamin E is administered at the dose of 3 units per kilogram of the baby's weight per

day. This medicine is manufactured by Behsa Company and is given to the neonates for 6 days. In the control group, the same placebo will be used.

Main outcome variables

Creatinine level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221220056875N1**

Registration date: **2023-04-08, 1402/01/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-08, 1402/01/19**

Update count: **0**

Registration date

2023-04-08, 1402/01/19

Registrant information

Name

Najme sadat Pishnamazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4412 6850

Email address

najme.pnz7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-20, 1401/12/29

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin E in the prevention of acute renal failure in infants weighing more than 1000 admitted to the neonatal intensive care unit

Public title

Investigating the effect of vitamin E in the prevention of kidney dysfunction in infants

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalized in the neonatal intensive care unit Weight more than 1000 grams Not having any congenital or chromosomal abnormalities

Exclusion criteria:

Allergy to vitamin E Contraindications for vitamin E use Lack of consent to participate in the study

Age

To 30 days old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type will be simple randomization. 150 envelopes of the same shape and size with black and white inner beads will be selected. Then these 150 envelopes are mixed. When the patient visits according to the conditions of entering the study, the researcher will take out an envelope, and if the inner bead is black, the patient will enter the control group, and if the bead is white, the patient will enter the intervention group. This envelope will be stored in another box. This will be repeated 150 times.

Blinding (investigator's opinion)

Double blinded

Blinding description

People from the research team who are responsible for nursing and prescribing drugs to patients will not know about the groups. Also after consent form approval, neither patients nor their companions were informed about patients group of control and intervention. Also in control group we will use placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Basij Square, Arak, Iran

City

Tehran

Province

Tehran

Postal code

3848176941

Approval date

2023-01-14, 1401/10/24

Ethics committee reference number

IR.ARAKMU.REC.1401.313

Health conditions studied**1****Description of health condition studied**

Acute kidney failure

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

Primary outcomes**1****Description**

Creatinine

Timepoint

before the treatment and on the second, fourth and sixth days after starting the treatment

Method of measurement

Blood sampling is done from the patients and the creatinine level is determined by a laboratory kit.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Vitamin E is prescribed at the dose of 3 units per kilogram of the baby's weight per day. This drug is manufactured by Behsa Company and is given to neonates for 6 days.

Category

Prevention

2

Description

Control group: The same placebo will be used in this group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amir Kabir Hospital

Full name of responsible person

Parsa Yousefichaijan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Najmeh Sadat Pishnamazi

Position

Resident

Latest degree

Specialist

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable