Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the vitamin C and thiamine administration method with the usual method in the improvement and prognosis of shock patients 1 month to 15 years

Protocol summary

Study aim

Determining and comparing the effect of vitamin C and thiamine administration method with the usual method in the improvement and prognosis of shock patients one month to 15 years

Design

A randomized, double-blinding clinical trial, with parallel groups, Phase 3 on 270 patients

Settings and conduct

In this randomized double-blind clinical trial study, 270 eligible patients referred to Imam Hossein Hospital of Isfahan will be included in the study and will be randomly divided into three groups. In the first, second, and third groups, "vitamin c", "thiamine" and "normal saline" are prescribed respectively. Then, the need for a vasopressor and a ventilator, and the level of blood parameters of the patients will be evaluated and compared among the three groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria include children 1 month to15 years old, suffering from shock, needing vasopressors to maintain at least 5% blood pressure percentile for age, and parental consent to participate in the study. Exclusion criteria include active gastrointestinal bleeding.

Intervention groups

The first intervention group: For patients in this group, vitamin C medicine will be prescribed at a dose of 30 mg/kg every 6 hours up to a maximum of 1500 mg/dose for 4 days or until hospitalization in PICU. The second intervention group: For patients in this group, oral thiamine medicine will be prescribed at a dose of 4 mg/kg every 12 hours up to a maximum of 200 mg/kg/dose for 4 days or until admission to the PICU. Control group: For patients in this group, normal saline with the same volume and form of the study drugs will be prescribed with the same protocol.

Main outcome variables

Vasopressor dose; Ventilator requirement; Blood Creatinine level; white blood cell level; C-reactive protein or CRP level; Lactate level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N61**
Registration date: **2022-10-14, 1401/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-14, 1401/07/22**
Update count: **0**

Registration date

2022-10-14, 1401/07/22

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the vitamin C and thiamine administration method with the usual method in the improvement and prognosis of shock patients 1 month to 15 years

Public title

The effectiveness of vitamin C and thiamine administration method in the improvement and prognosis of shock patients 1 month to 15 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children from 1 month to 15 years Suffering from shock (other than obstructive shock) Need vasopressors to maintain at least 5% of blood pressure percentile for age Parents' consent to participate in the study

Exclusion criteria:

Having active gastrointestinal bleeding

Age

From **1 month** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **270**

Randomization (investigator's opinion)

Randomized

Randomization description

Before starting the study, letter A is written on 90 sheets, letter B is written on 90 sheets, and letter C is written on 90 sheets and each is placed in an envelope. Then, the parents of each of the eligible patients who consented to participate in the study are asked to choose an envelope from among the envelopes. In this way, the patient will be randomly assigned to one of the three groups according to the envelope selected without the interference of the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to comply with the conditions of double-blindness of the study, vitamin C, thiamine, and placebo were prepared by the pharmacist in the same shape, color, and size before the study (without the researcher's knowledge) and are placed in the same packaging and with A, B, C codes are labeled. Then the drugs are provided to the researcher and the researcher will prescribe them in the same way without knowing the type of drug. Therefore, the patient, care provider, investigator, outcome assessor, and data analyzer will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-01-20, 1400/10/30

Ethics committee reference number

IR.MUI.MED.REC.1400.751

Health conditions studied

1

Description of health condition studied

Shock

ICD-10 code

R57.9

ICD-10 code description

Shock, unspecified

Primary outcomes

1

Description

The amount of Vasopressor requirement

Timepoint

During the intervention

Method of measurement

Number of vasopressor injections

2

Description

Ventilator requirement

Timepoint
During the intervention
Method of measurement
PaCo2<50% and pH<7.3

Secondary outcomes

1

Description
Blood Creatinine
Timepoint
In the first four days of hospitalization
Method of measurement
Blood test

2

Description
C-reactive protein (CRP)
Timepoint
In the first four days of hospitalization
Method of measurement
Blood test

3

Description
White blood cell
Timepoint
In the first four days of hospitalization
Method of measurement
Blood test

4

Description
Lactate
Timepoint
In the first four days of hospitalization
Method of measurement
Blood test

Intervention groups

1

Description
First intervention group: For patients in this group, vitamin C medicine will be prescribed at a dose of 30 mg/kg every 6 hours up to a maximum of 1500 mg/dose for 4 days or until admission to the PICU.
Category
Treatment - Drugs

2

Description
The second intervention group: For patients in this group, oral thiamine medicine will be prescribed at a dose of 4 mg/kg every 12 hours up to a maximum of 200 mg/kg/dose for 4 days or until admission to the PICU.
Category
Treatment - Drugs

3

Description
Control group: For patients in this group, normal saline with the same volume and form of the study drugs will be prescribed with the same protocol.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital in Isfahan
Full name of responsible person
Nazanin Zibanejad
Street address
Imam Khomeini street
City
Isfahan
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Postal code
8195163381
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zibanejadn@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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8174673461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source

Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Nazanin Zibanejad

Position
Assistance professor

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Department of Pediatrics, Imam Hossein Hospital, Imam Khomeini Street.

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available