

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 to 15 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

Isfahan

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

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Imam Khomeini street

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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?**

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
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Pediatrics
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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