Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of norepinephrine with and without dobutamine on mortality and morbidity of children with septic shock admitted to the intensive care unit

Protocol summary

Study aim
Comparison of the effect of norepinephrine with and without dobutamine in mortality and morbidity of children with septic shock hospitalized in the intensive care unit

Design
Clinical trial with two intervention groups, with parallel groups, single-blind, randomized, phase 2 on 40 patients. R statistical software is used for block randomization.

Settings and conduct
This clinical trial, which is conducted in Shahid Bahoner Hospital, Kerman, on 40 children with septic shock admitted to the intensive care unit, is a single-blind study, so that the results are checked by an anesthetist, nurse, and uninformed laboratory personnel.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children in the age group of 2 to 14 years children with septic shock They need to transfer to the intensive care unit Non-inclusion criteria: Children with organ failure The patient's lack of consent, or if the patient is unable to answer, the patient's guardian's lack of consent The presence of heart failure, kidney and diabetes

Intervention groups
The first intervention group receives norepinephrine in addition to common supportive measures, and the second group receives norepinephrine with dobutamine.

Main outcome variables
Hospitalization period; number of days dependent on vasopressor; Hemodynamic and perfusion findings (CO-MAP-HR); serum lactate level; Electrolytes (urea and creatinine)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101220005426N13**
Registration date: **2023-01-26, 1401/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-26, 1401/11/06**
Update count: **0**

Registration date
2023-01-26, 1401/11/06

Registrant information

Name
Mehdi Ahmadinejad

Name of organization / entity
Anesthesiology department, Kerman University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-23, 1401/11/03

Expected recruitment end date
2023-02-22, 1401/12/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of norepinephrine with and without dobutamine on mortality and morbidity of children with septic shock admitted to the intensive care unit

Public title

Comparison of the effect of norepinephrine with and without dobutamine on mortality and morbidity of children with septic shock

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children in the age group of 2 to 14 years Children with septic shock They need to transfer to the intensive care unit

Exclusion criteria:

Children with organ failure The patient's lack of consent, or if the patient is unable to answer, the patient's guardian's lack of consent The presence of heart failure, kidney and diabetes

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize people to the two groups, the block randomization method is used in such a way that 4 blocks are used. In each block of 4, 2 people are assigned to the first group and 2 people to the second group. R statistical software is used for random block allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

It is a one-sided blind method, so that the vasopressor is prescribed by the ICU specialist. Cardiac examination (cardiac indices) will be done by a pediatric cardiologist and HR-MAP and urinary tract examination will be done by the senior ICU nurse who does not know the type of vasopressor injection to the patients. Also, laboratory tests will be performed by a technician unaware of the interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee, Kerman University of Medical Sciences

Street address

At the beginning of Jihad Blvd., Research Deputy of Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2022-10-09, 1401/07/17

Ethics committee reference number

IR.KMU.AH.REC.1401.147

Health conditions studied

1

Description of health condition studied

Septic shock

ICD-10 code

T81.12

ICD-10 code description

Postprocedural septic shock

Primary outcomes

1

Description

Hemodynamic and blood supply findings (CO-MAP-HR)

Timepoint

Measuring CO-MAP-HR at the beginning of the study (before the intervention) and then every hour until the end of the study

Method of measurement

Ecocardiography

2

Description

Vasopressor dependence days

Timepoint

The number of days that patients receive vasopressor

Method of measurement

Check list

3

Description

Urinary tract

Timepoint

At the beginning of the study and then every 6 hours until the end of the study

Method of measurement
Check list

4

Description
Duration of hospitalization in the intensive care unit
Timepoint
At the beginning of the study and then daily until the end of hospitalization in the relevant department
Method of measurement
Check list

5

Description
Serum lactate level
Timepoint
At the beginning of the study, then daily until the end of the study
Method of measurement
AutoAnalyzer

6

Description
Electrolytes (urea, creatinine)
Timepoint
At the beginning of the study, then daily until the end of the study
Method of measurement
AutoAnalyzer

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The first group receives epinephrine at a dose of 0.1 to 1 mcg/kg in addition to common supportive treatments.
Category
Treatment - Other

2

Description
Intervention group: The second group, in addition to common support treatments, receive epinephrine at a dose of 0.1 to 1 mcg/kg along with 5 mcg/kg of dobutamine.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital, Kerman
Full name of responsible person
Mehdi Ahmadinejad
Street address
Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Reza Malekpour Afshar
Street address
Kerman, Shariati St., Vali Asr Chaharah, Qorani St., Shahid Bahonar Hospital
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Kerman University of Medical Sciences
Position
Assistant Professor- Fellow of Intensive Care
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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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
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