

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of dopamine and dobutamine on children with hypotension admitted to the intensive care unit.

Protocol summary

Study aim

Comparison of the effects of dopamine and dobutamine on children with hypotension admitted to the intensive care unit.

Design

This clinical trial has three parallel groups in phase 2-3 which were performed on 81 randomly selected patients. In group 1, dopamine at a dose of 10 min µgr / kg, in the second group, dobutamine at a dose of 10 min µgr / kg, and in the third group, a combination of these two drugs was used.

Settings and conduct

In this clinical trial, 81 children with hypotension admitted to the NICU and PICU intensive care units of Amirkabir and Taleghani hospitals in Arak in 1398 were randomly divided into three groups. In the first group dopamine at a dose of 10 minutes / kg micrograms and in the second group dobutamine at a dose of 10 kg / kg / micrograms and in the third group a combination of these two drugs was used. The recorded results before and after treatment with dopamine and dobutamine were compared and statistically analyzed.

Participants/Inclusion and exclusion criteria

All children under 15 with hypotension without any underlying disease including malignancies and other chronic diseases

Intervention groups

In this study, 81 children who meet the inclusion criteria are selected. The inclusion criteria for this assessment include patients under the age of 15 who are hospitalized in the intensive care unit and their parents are willing to participate in the study. After obtaining their informed consent, the patients enter the study. Patients are randomly assigned to three categories: 27 children in the dopamine group, 27 children in the dobutamine group, and 27 children in the dopamine + dobutamine group.

Main outcome variables

Hypotension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210116050051N1**

Registration date: **2021-09-25, 1400/07/03**

Registration timing: **retrospective**

Last update: **2021-09-25, 1400/07/03**

Update count: **0**

Registration date

2021-09-25, 1400/07/03

Registrant information

Name

Naser kashefi sis

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 4242 2457

Email address

dr.kashefi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-12-20, 1397/09/29

Actual recruitment start date

2018-05-20, 1397/02/30

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-12-22, 1398/10/01

Scientific title

Comparison of the effects of dopamine and dobutamine on children with hypotension admitted to the intensive care unit.

IR.ARAKMU.REC.1398.256

Public title

Comparison of the effects of dopamine and dobutamine on children with hypotension admitted to the intensive care unit.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children under 15 with hypotension without any other underlying disease

Exclusion criteria:

Children over 15 years Children with underlying disease Children with malignancies

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **81**

Actual sample size reached: **81**

Randomization (investigator's opinion)

N/A

Randomization description

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

Arak University of Medical Sciences

Street address

Amirkabir Hospital

City

arak

Province

Markazi

Postal code

3819693345

Approval date

2020-01-30, 1398/11/10

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Hypotension

ICD-10 code

I95

ICD-10 code description

Hypotension

Primary outcomes

1

Description

Blood pressure measurement in children using monitoring

Timepoint

It is recorded 24 hours a day, using monitoring during the hospital stay

Method of measurement

monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: Dopamine at a dose of 10 kg / dose µgr daily during hospitalization until appropriate blood pressure is reached

Category

Treatment - Other

2

Description

Group 2 : dobutamine with a dose of 10kg / dose µgr daily during hospitalization until appropriate blood pressure is reached

Category

Treatment - Drugs

3

Description

Group 3: combination of dobutamine with a dose of 10 kg / dose µgr and dopamine with a dose of 10 kg / dose µgr daily during hospitalization until appropriate blood pressure is reached

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care unit of Amirkabir Hospital in Arak

Full name of responsible person

Nasser Kashefi Sis

Street address

Amirkabir Hospital, Arak

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Phone

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Email

Dr.kashefi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Street address

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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

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

Nasser Kashefi Sis

Position

pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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

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

Title and more details about the data/document

All data can be shared after people are not identified

When the data will become available and for how long

Access period starts from 2020

To whom data/document is available

Researchers working in academic centers

Under which criteria data/document could be used

Data analysis is allowed in order to publish scientific texts by mentioning the source.

From where data/document is obtainable

dr.kashefi@gmail.com - dr.Kashefi Naser sis

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

The e-mail sent by the applicant will be answered

Comments