

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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  $\mu\text{g}/\text{kg}$ , in the second group, dobutamine at a dose of 10 min  $\mu\text{g}/\text{kg}$ , 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  $\mu$ gr daily during hospitalization until appropriate blood pressure is reached

#### Category

Treatment - Other

### 2

#### Description

Group 2 : dobutamine with a dose of 10kg / dose  $\mu$ gr 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  $\mu$ gr and dopamine with a dose of 10 kg / dose  $\mu$ gr 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

**City**

arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 41 4242 2457

**Email**

Dr.kashefi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Nasser Kashefi Sis

**Street address**

Amirkabir Hospital, Arak

**City**

arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

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**Email**

Dr.kashefi@gmail.com

**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

**Street address**

Amirkabir Hospital, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 41 4242 2457

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Dr.kashefi@gmail.com

## Person responsible for scientific 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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**Email**

Dr.kashefi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Nasser Kashefi Sis

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Amir Kabir Hospital, Arak

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**Postal code**

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**Email**

Dr.kashefi@gmail.com

**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**