

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of epinephrine in combination with methylprednisolone on neurological complications and the need for vasopressor after resuscitation in patients with cardiopulmonary arrest

Protocol summary

Study aim

Comparison of the effect of epinephrine in combination with methylprednisolone on neurological complications and the need for vasopressor after resuscitation in patients with cardiopulmonary arrest

Design

This study is double-blinded clinical trial. The study population will be included all patients suffering from cardiac arrest refer to emergency department of Imam Reza hospital of Kermanshah. 342 eligible patients will be selected conveniently and randomly will be assigned to intervention and control groups.

Settings and conduct

This study, which will be conducted at Imam Reza hospital of Kermanshah, is double-blinded one. Participants and researchers will be unaware and keep blinded to the allocation of study groups. Methylprednisolone and normal saline will be prepared in similar syringes, and the injector only performs the injection according to the specific code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Above 18 years old ; No previous neurological disorders
Exclusion criteria: Patients who do not have the possibility of injections during recovery due to the lack of peripheral blood vessels; Patients with respiratory cardiac arrest outside the hospital

Intervention groups

The intervention group, in addition to receiving one mg of epinephrine, in each respiratory resuscitation cycle will receive 125 mg intravenous methylprednisolone every 3 to 5 minutes later. The control group, in addition to receiving one mg of epinephrine, in each respiratory resuscitation cycle, every 3 to 5 minutes later will received 125 mg intravenous normal saline as placebo .

Main outcome variables

Neurological complications; Hypertension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N127**

Registration date: **2019-07-27, 1398/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-27, 1398/05/05**

Update count: **0**

Registration date

2019-07-27, 1398/05/05

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2019-08-16, 1398/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Medical Sciences
Scientific title	Street address
Comparison of the effect of epinephrine in combination with methylprednisolone on neurological complications and the need for vasopressor after resuscitation in patients with cardiopulmonary arrest	Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
Public title	City
Comparison of the effect of epinephrine in combination with methylprednisolone on neurological complications in patients with cardiopulmonary arrest	Kermanshah
Purpose	Province
Treatment	Kermanshah
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	6715847141
Above 18 years old No previous neurological disorders Cardiopulmonary arrest	Approval date
Exclusion criteria:	2019-04-24, 1398/02/04
Patients who do not have the possibility of injections during recovery due to the lack of peripheral blood vessels Patients with cardiopulmonary arrest outside the hospital	Ethics committee reference number
Age	ir.kums.rec.1398.107
From 18 years old	Health conditions studied
Gender	1
Both	Description of health condition studied
Phase	Cardiopulmonary arrest
3	ICD-10 code
Groups that have been masked	I46
- Participant - Investigator	ICD-10 code description
Sample size	Cardiac arrest
Target sample size: 342	Primary outcomes
Randomization (investigator's opinion)	1
Randomized	Description
Randomization description	Neurological complications
Randomly Individually by random number table via code receipt.	Timepoint
Blinding (investigator's opinion)	24 hours after resuscitation
Double blinded	Method of measurement
Blinding description	Based on a doctor's Checking out and according to Cerebral performance category.
In this study, participants and researchers are unaware and will be keep blinded to the allocation of study groups	2
Placebo	Description
Used	hypertension
Assignment	Timepoint
Parallel	24 hours after resuscitation
Other design features	Method of measurement
	Using Digital Blood Pressure
Secondary Ids	3
empty	Description
Ethics committees	Rhythm during resuscitation
1	Timepoint
Ethics committee	24 hours after resuscitation
Name of ethics committee	Method of measurement
Ethics committee of Kermanshah University of	Using a heart rhythm monitoring device
	Secondary outcomes
	empty

Intervention groups

1

Description

The intervention group, in addition to receiving one mg of epinephrine, in each respiratory resuscitation cycle, every 3 to 5 minutes later will received 125 mg intravenous methylprednisolone .

Category

Treatment - Drugs

2

Description

The intervention group, in addition to receiving one mg of epinephrine, in each respiratory resuscitation cycle, every 3 to 5 minutes later will received 125 mg intravenous normal saline as placebo .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Nasrin Bahrami

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Rejimdarmani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice chancellor for research of Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Nasrin Bahrami

Position

Resident of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Emam Reza Hospital, Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6330

Email

Rejimdarmani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hooman Rafee Surori

Position

Member of the faculty of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6330

Email

Hooman_rafiee@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Nasrin Bahrami

Position

Resident of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Emam Reza Hospital, Parastar Blvd

City

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Province

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Postal code

6715847141

Phone

+98 34276330

Email

Rejimdarmani@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Sharing scientific data is available to researchers

From where data/document is obtainable

To receive the documentation, email send for update manager Email: Rejimdarmani@yahoo.com

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

In a 15-day period, the documents will be sent e-mail

Comments