Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 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. Methyl prednisolone 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

Scientific title
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

Public title
Comparison of the effect of epinephrine in combination with methylprednisolone on neurological complications in patients with cardiopulmonary arrest

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Above 18 years old No previous neurological disorders Cardiopulmonary arrest

Exclusion criteria:
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

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **342**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly Individually by random number table via code receipt.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants and researchers are unaware and will be keep blinded to the allocation of study groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2019-04-24, 1398/02/04

Ethics committee reference number
ir.kums.rec.1398.107

Health conditions studied

1

Description of health condition studied
Cardiopulmonary arrest

ICD-10 code
I46

ICD-10 code description
Cardiac arrest

Primary outcomes

1

Description
Neurological complications

Timepoint
24 hours after resuscitation

Method of measurement
Based on a doctor's Checking out and according to Cerebral performance category.

2

Description
hypertension

Timepoint
24 hours after resuscitation

Method of measurement
Using Digital Blood Pressure

3

Description
Rhythm during resuscitation

Timepoint
24 hours after resuscitation

Method of measurement
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 received125 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
Kermanshah
Province
Kermanshah
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