Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of intravenous bolus Ephedrine and Norepinephrine for the reduction of Hypotension in general Anesthesia in patient with Hypertension

Protocol summary

Study aim

To compare the efficacy of intravenous bolus Nor epinephrine in compensating for hypotension during general anesthesia with intravenous Ephedrine

Design

56Patients who undergo general anesthesia for spinal surgery who have MAP below 60 millimeter Hg, are randomly divided into Ephedrine and Nor epinephrine groups.

Settings and conduct

The patients are selected in Rasool Akram Hospital operating room.For treatment of hypotension an Ephedrine dose of 5 milligram is injected into the Ephedrine group and MAP is recorded after 5 minutes. An Nor epinephrine dose of 10 microgram is injected into the Nor epinephrine group and MAP is recorded after 2 minutes. In each group, if MAP does not reach 60, the dose is repeated up to 3 times.Changes in MAP, Heart Rate and frequency of drug injection are compared in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-75 years old؛ History of Hypertension؛ Patients undergo general anesthesia for spinal surgery؛ MAP below 60 millimeter Hg during anesthesia Exclusion criteria: History of cardiac arrhythmia؛ valvular heart disease ؛ cerebral vascular disease؛ renal failure ؛ diabetes؛ Using Beta blocker drugs

Intervention groups

Ephedrine group:1 milliliter of Ephedrine 5 milligram per milliliter Nor epinephrine group; 1 Milliliter of Nor epinephrine 10 micrograms per milliliter

Main outcome variables

Mean Arterial Pressure Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038296N1**
Registration date: **2018-01-28, 1396/11/08**
Registration timing: **retrospective**

Last update: **2018-06-23, 1397/04/02**
Update count: **1**

Registration date

2018-01-28, 1396/11/08

Registrant information

Name

Sahar Masghati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86709

Email address

masghati.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-01-04, 1395/10/15

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of intravenous bolus

Ephedrine and Norepinephrine for the reduction of Hypotension in general Anesthesia in patient with Hypertension

Public title
Effect of Ephedrine and Norepinephrine in treatment of hypotension in general anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 ti 75 years old History of Hypertension General anesthesia in spinal surgery Mean arterial pressure below 60 millimeter Hg during anesthesia
Exclusion criteria:
History of cardiac arrhythmia History of valvular heart disease History of cerebral vascular disease History of renal failure Use Beta blocker drugs History of diabetes
Age
From **20 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **56**
Actual sample size reached: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and Care workers
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences Sciences
Street address
Next to Milad Tower., Hemmat HighWay
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-05-23, 1396/03/02
Ethics committee reference number
IR.IUMS.REC 1396.9311174021

Health conditions studied

1

Description of health condition studied
Hypotension
ICD-10 code
I95.9
ICD-10 code description
Hypotension, unspecified

Primary outcomes

1

Description
Mean Arterial Pressure
Timepoint
During Anesthesia
Method of measurement
Radial artery catheter

2

Description
Heart rate
Timepoint
During anesthesia
Method of measurement
Using a monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Ephedrine Group: After a mean arterial pressure (MAP) drop to less than 60 millimeter Hg، one milliliter of Ephedrine with a concentration of five milligrams per milliliter، is injected intravenous bolus.
Category
Treatment - Drugs

2

Description
Intervention group: :Norepinephrine Group : After a mean arterial pressure (MAP) drop to less than 60 millimeter Hg، one milliliter of Norepinephrine with a

concentration of 10 micrograms per milliliter، is injected intravenous bolus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Sahar Masghati

Street address

Niayesh Ave.,Satarkhan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Sahar Masghati

Position

Anesthesiology assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Valiollah Hassani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences
Full name of responsible person
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Position
Anesthesiology Assistant
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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
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Information about the main outcome will be shared.
When the data will become available and for how long
Start the access period 6 months after printing the results.
To whom data/document is available
Data will only be available to researchers working in academic institutions.
Under which criteria data/document could be used
The documentation is for use in research projects only.
From where data/document is obtainable
Dr Sahar Masghati :saharmasghati@gmail.com
What processes are involved for a request to access data/document
To receive documentation, send email to Dr Sahar Masghati .Data will be sent within 3 months.
Comments