

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

56 Patients 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 to 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

City

Tehran

Province

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1445613131

Phone

+98 21 6435 2326

Email

saharmasghati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Kazem Malakooti

Street address

Next to Milad Tower, Hemmat Highmay

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1449614535

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Email

PR@iums.ac.ir

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

Iran University of Medical Sciences

Full name of responsible person

Valiollah Hassani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Email

valiollah-hassani@yahoo.com

Person responsible for updating data

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

Street address

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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