Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anesthesiain patients undergoing hip fracture surgery.

Protocol summary

Study aim

Comparison of the effect of norepinephrine infusion versus phenylephrine in preventing hemodynamic changes following spinal anesthesia in patients undergoing hip fracture surgery.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3 on 125 patients. www.sealedenvelope.com is used for randomization.

Settings and conduct

This double-blind clinical trial study will be conducted on 125 patients undergoing hip fracture surgery in two groups at Sina Hospital in Tehran. Random allocation of samples is done by block method. A digital monitor will be used to measure blood pressure and heart rate. Questionnaires will be completed and variables will be recorded by the research team during the operation and at the designated times.

Participants/Inclusion and exclusion criteria

Conditions for entering the study include: patients over 50 years of age who are candidates for hip fracture surgery, who can receive spinal anesthesia according to the anesthesiologist's opinion and are willing to undergo spinal anesthesia. Conditions for exclusion from the study: the patient's inability to be in the right position or the presence of any contraindications for spinal anesthesia and the need for general anesthesia according to the anesthesiologist's opinion and failure of spinal anesthesia.

Intervention groups

Intervention group: patients who receive intravenous infusion of epinephrine (8µg/min) immediately after spinal anesthesia until the end of the operation. Control group: patients who receive intravenous phenylephrine infusion (50 µg /min) immediately after spinal anesthesia until the end of the operation.

Main outcome variables

Systolic blood pressure; diastolic blood pressure; mean blood pressure; heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220513054842N1**
Registration date: **2022-10-30, 1401/08/08**
Registration timing: **prospective**

Last update: **2022-10-30, 1401/08/08**
Update count: **0**

Registration date

2022-10-30, 1401/08/08

Registrant information

Name

Mohamadreza Neishaboury

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4427 2306

Email address

mrneishaboury@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2024-02-01, 1402/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anesthesiain patients undergoing hip fracture surgery.

Public title

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anesthesia for patients undergoing hip fracture surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing hip fracture surgery who need spinal anesthesia according to the anesthesiologist's opinion Age older 50 years old Patient's consent to perform spinal anesthesia

Exclusion criteria:

The patient's inability to be in the right position or the presence of any contraindications for spinal anesthesia The need for general anesthesia according to the anesthesiologist Failure of spinal anesthesia

Age

From **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **125**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method will be used for the random allocation of patients,and the website www.sealedenvelope.com will be used.The website creates blocks randomly (keeping in mind that the number of study groups in each block is equal) and the number of generated blocks will be 35.Then he provides them as an Excel output to the random person. Only the anesthesiologist knows about the grouping of the patients and prepares the medicine needed for each group anonymously in the microset and provides it to the anesthesiologist (project manager).Enrollment in the study is determined based on the blocks made in order.For example, if the first quadruple block generated is norepinephrine/phenylephrine/phenylephrine/norepinephrine, the first and fourth patients are entered into the norepinephrine group and the second and third patients are entered into the phenylephrine group.The determination of the group was done by the anesthesiologist and the researchers will not know about this process and the structure of the blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researched drugs are similar in color and are prepared anonymously with a special code by a nurse of anesthesia who is not involved in the research team.She records the syringe code, date, and patient file number in her notebook and keeps it with her until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Sina Hospital, Tehran University of Medical Sciences

Street address

Sinai Hospital, Imam Khomeini Street

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2022-08-02, 1401/05/11

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1401.053

Health conditions studied

1

Description of health condition studied

Hypotension after spinal anesthesia

ICD-10 code

I95.81

ICD-10 code description

Postprocedural hypotension

Primary outcomes

1

Description

Blood pressure

Timepoint

Every 3 minutes

Method of measurement
Digital pressure gauge

2

Description
Heart Rate
Timepoint
Continuously
Method of measurement
ECG monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After spinal anesthesia for hip surgery, intravenous infusion of norepinephrine 5 micrograms per minute is started.
Category
Prevention

2

Description
Control group: After spinal anesthesia for hip surgery, intravenous infusion of phenylephrine 50 µg/min is started.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr. Mohammad Reza Neishaburi
Street address
Sinai Hospital, Imam Khomeini St
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8550
Email
mrneishaboury@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fatuhi
Street address
Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3686
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Neishaboury
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Sinai Hospital,Imam Khomeini Street
City
Tehran
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Main outcome data of the study

When the data will become available and for how long
6 months after completing the study

To whom data/document is available
University researchers

Under which criteria data/document could be used
Sharing scientific findings to increase the production of science

From where data/document is obtainable
Email address of Dr. Nishaboury:mrnishaboury@tums.ac.ir

What processes are involved for a request to access data/document
The request should be made by email and the answer will be given within two months

Comments