

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anesthesia in 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 anesthesia in 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

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8550

Email

mrneishaboury@tums.ac.ir

Person responsible for scientific 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

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8550

Email

mrneishaboury@tums.ac.ir

Person responsible for updating data

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

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8550

Email

mrneishaboury@tums.ac.ir

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