Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of mean arterial blood pressure and heart rate in both groups of patients undergoing percutaneous nephrolithotomy surgery (PCNL) with general anesthesia or spinal anesthesia.

Protocol summary

Summary

Objectives: This study is aimed to compare the mean arterial pressure and heart rate in both groups of patients undergoing general anesthesia versus spinal anesthesia during percutaneous nephrolithotomy (PCNL) surgery. Design: Prospective randomized clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: Sixty patients, with age 18-65yr; ASA Class I- II, undergoing PCNL in Shahid Hasheminejad Hospital during 2011-2012,were included . Patients were randomized into two groups of 30 each, using a table of random numbers. Intervention: control group , patients undergoing general anesthesia,Induced anesthesia with 3-5 mg/kg thiopental sodium and maintenance of anesthesia was achieved with propofol (100 mic/kg/min), and Study group , patients undergoing spinal anesthesia received 15-20 mg intrathecal bupivacaine isobar 0.5%. Main outcome measures (variables): Postoperative Visual analog scale (VAS); Blood pressure; Heart rate; Blood loss volume; Analgesic requirement, The need transfusion during recovery and ward. The technique of anesthesia are coded and delivered to the patients by and individual not aware of the research process. A stuff assessed Postoperative VAS; Blood pressure; Heart rate; Blood loss volume; Analgesic requirement, The need blood transfusion

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212228435N2**
Registration date: **2013-01-16, 1391/10/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-16, 1391/10/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of mean arterial blood pressure and heart rate in both groups of patients undergoing percutaneous nephrolithotomy surgery (PCNL) with general anesthesia or spinal anesthesia.

Public title

Comparing the efficacy of general anesthesia and spinal anesthesia on blood pressure and heart rate changes in renal stone surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria of study: Age 18-65 yr;ASA Class I- II
Exclusion criteria of study: Contraindication for spinal anesthesia; Taking any pain medication 24 hours before surgery; Sensitivity to drug study; Substance abuse; Neurologic disease or neuromuscular or psychiatric disease; Chronic pain syndrome; Diabetes mellitus,hypertension,cardiovascular disease,coagulopathy disease; Injection of analgesic during spinal anesthesia; Pregnancy ; Sensory level above T4 or below T10

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences and Health Services

Street address

Poursina Ave.

City

Tehran

Postal code

Approval date

2011-03-20, 1389/12/29

Ethics committee reference number

p/29-12-89

Health conditions studied

1

Description of health condition studied

Percutaneous nephrolithotomy

ICD-10 code

N20.0, N13

ICD-10 code description

First diagnosis of kidney stones

Primary outcomes

1

Description

Mean Arterial Blood Pressure

Timepoint

Intraoperative and Recovery

Method of measurement

mm Hg

2

Description

Heart Rate

Timepoint

Intraoperative and Recovery

Method of measurement

Number /min.

Secondary outcomes

1

Description

Consumption of Analgesic Amount

Timepoint

Recovery

Method of measurement

mg

2

Description

The need of blood transfusion

Timepoint

Intraoperative

Method of measurement

The volume of blood transfused in CC

3

Description

Intraoperative bleeding

Timepoint

Intraoperative

Method of measurement

Measured with the blood suctioned in cc by the graded container

Intervention groups

1

Description
In the study group, Spinal anesthesia, 15-20 mg intrathecal bupivacaine isobar 0.5%
Category
Prevention

2

Description
In the control group, General anesthesia, Induced anesthesia with 3-5 mg/kg thiopental sodium and maintenance of anesthesia was achieved with propofol (100 mic/kg/min).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Hasheminejad Hospital
Full name of responsible person
Valiallah Hassani
Street address
Valinejad Ave. above Vanak Squ. Valiasr St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences and Health Services
Full name of responsible person
Shahin Akhunzadeh MD.
Street address
Poursina St.
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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
Vice chancellor for research, Tehran University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty