

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

A comparison hemodynamic change of minidose lidocaine-fentanil and conventional-dose lidocaine spinal anesthesia in patient with controlled systemic hypertension for TURP surgery

Protocol summary

Summary

Spinal anesthesia (SA) is the choice method of anesthesia for Prostate gland surgery through urinary tract (Trans Urethral Resection of the Prostate- TURP). In conventional method of SA, which we ordinarily use 2 CC lidocaine 5% (100 mg), there are many dangerous complications in elderly patients such as ischemic heart disease, cardio-vascular collapse, Acute Tubular Necrosis (ATN) or even Acute Renal Failure (ARF). These complications may be occurred especially among patients who have cardio-vascular diseases such as systemic hypertension. As a result, the patients' morbidity and mortality may be increased. Neuro-axial usage of local anesthetic drugs such as lidocaine may create hypotension via blocking sympatic fibers. To solve this problem, we could decrease lidocaine dosage together with drugs, simultaneously. We could solely use narcotic drugs, because hypotension do not occurs subsequent of neuro-axial usage of narcotic drugs. In this Double-blind Randomized Clinical Trial (RCT) study, we will compare anesthetic effects of a combination of anesthetic-narcotic drugs with the ordinary method. Doing spinal anesthesia, we will use 1 CC lidocaine 5% (50 mg) together with 1 CC fentanil (50 mcg) in treatment group. We hope this drug combination not only create a relevant painless level for the patients, but also inhibit hemodynamic variability. Therefore, we could expect to reduce morbidity and mortality resulted from the hemodynamic variability. This will be a double-blind RCT. It means both the patients and the evaluators will not know which patient receive which treatment will. Study population will be the candidate patients of TURP surgery. The inclusion criteria will be hypertensive patients age 50 and older who admit in the 15-Khordad hospital with Benign Prostate Hyperplasia (BPH). There will be some exclusion criteria consisting of patient's inability to immobility when interning spinal needle;

increasing Intra Cranial Pressure (ICP); coagulation disorders; skin or soft tissue infection in the spinal site; instability in hemodynamic features. Demographic characteristics of all samples will be initially registered. Then, normal/saline serum (5cc/kg) will be infused for each patient. They will be also monitored concerning blood pressure and heart rate. Electro Cardio Graph (ECG) and pulse-oximetry will be done for all the samples. To implement SA, we will randomly assign the patients in the treatment (1 CC lidocaine + 1 CC Fantanil) and control (2 CC lidocaine) groups. The injections will be done through L4-L5 or L5-S1 intra-vertebral areas. The patients' BP and HR will be measured and recorded after spinal anesthesia and every 5 minutes. Major hypotension (descending BP greater than 20% of basic BP) and bradycardia (HR lower than 45/min) will be treated with ephedrine and atropine, respectively. PRBC transfusion will be done in patients with excessive bleeding. These patients will be excluded from the study. According to previous similar studies, we determined 148 samples (74 samples for each group) in this research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107207064N1**

Registration date: **2011-09-17, 1390/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-09-17, 1390/06/26

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gonabad University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-04-18, 1391/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison hemodynamic change of minidose lidocaine-fentanil and conventional-dose lidocaine spinal anesthesia in patient with controlled systemic hypertension for TURP surgery

Public title

Comparison systemic blood pressure and heart rate change of two method spinal anesthesia in TURP surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age>50 years; controlled systemic hypertension; TURP surgery; ASA class II Exclusion criteria: patient refusal; patient inability to maintain stillness during the needle puncture; raised intracranial pressure; coagulopathy; skin or soft tissue infection at the proposed site of needle insertion; severe hypovolemia; opium addiction; lumbar disc herniation or surgery.

Age

From **50 years** old to **149 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Iran

City

Gonabad

Postal code

9691793718

Approval date

2011-07-09, 1390/04/18

Ethics committee reference number

90/32544

Health conditions studied**1****Description of health condition studied**

hemodynamic change of spinal anesthesia in patient with controlled systemic hypertension and age>50 years

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Systolic blood pressure

Timepoint

5 Min.

Method of measurement

Automatic cardioset monitoring

2**Description**

diastolic blood pressure

Timepoint

5 Min.

Method of measurement

Automatic cardioset monitoring

3

Description

heart rate

Timepoint

5 Min.

Method of measurement

Automatic cardioset monitoring

Secondary outcomes

1

Description

Ischemic heart disease and myocardial infarction

Timepoint

Every 8 Hr

Method of measurement

Serum CPK-MB and Troponin

2

Description

Acute tubular necrosis and acute renal failure

Timepoint

Daily

Method of measurement

Serum BUN and Creatinine

Intervention groups

1

Description

Spinal anesthesia with 1cc lidocaine 5% (50mg) + 1cc fentanyl 50 mcg (single dose). Lidocaine is a local anesthetic and fentanyl is a opium.

Category

Treatment - Drugs

2

Description

Spinal anesthesia with 2cc lidocaine 5% (100mg) single dose. Lidocaine is a local anesthetic.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

15 khordad hospital

Full name of responsible person

Sahebanmaleki Mohsen

Street address

15 Khordad Hospital, Gonabad, Iran

City

Gonabad

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research,Gonabad University of Medical Sciences

Full name of responsible person

Dr.Khosravan

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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,Gonabad University of Medical Sciences

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

Contact**Name of organization / entity**

Gonabad University Of Medical Sciences

Full name of responsible person

Sahebanmaleki Mohsen

Position

Anesthesiologist

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Web page address

Person responsible for updating data

Contact

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