Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-oximetery 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

Name

Mohsen Sahebanmaleki

Name of organization / entity
Gonabad University Of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 53 3725 1191
Email address
dr.saheban@gmu.ac.ir

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
Street address
Vice chancellor for research, Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Iran
City
Gonabad
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
Other areas of specialty/work
Street address
15 Khordad Hospital, Gonabad, Iran
City
Gonabad
Postal code
9691793718
Phone
+98 53 3723 1112
Fax
+98 53 3723 1116
Email
dr.saheban@gmu.ac.ir; dr.saheban@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University Of Medical Sciences

Full name of responsible person
Sahebanmaleki Mohsen

Position
Anesthesiologist

Other areas of specialty/work

Street address
15 Khordad Hospital, Gonabad, Iran

City
Gonabad

Postal code

Phone
+98 53 3723 1112

Fax

Email
dr.saheban@gmu.ac.ir; dr.saheban@yahoo.com

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