

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The comparison of analgesic and opioid- sparing effects of a preemptive single-shot epidural analgesia and unilateral single-injection Transversus Abdominis Plane block in patients undergoing renal surgeries

Protocol summary

Summary

Eighty patients (20-60 y), candidate for renal surgeries under general anesthesia, are enrolled after taking written informed consent. They are randomized to receive Epidural analgesia or TAP block for post-op pain management. In group A, the lumbar epidural catheter is placed for patients in sitting position, before induction of anesthesia and a total volume of 15 cc (4 cc Bupivacaine 0.5% and 11 cc pure water) is injected. In group B, TAP block catheter is placed for patients under ultrasound guide in supine position after induction of anesthesia and before surgical incision and the same volume of LA is injected. The same protocol of anesthesia with sodium thiopental and atracurium for induction and Propofol/Remifentanyl infusion for maintenance are performed for both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412063436N4**
Registration date: **2015-02-17, 1393/11/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-17, 1393/11/28

Registrant information

Name

Babak Gharaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Anesthesiology department, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of analgesic and opioid- sparing effects of a preemptive single-shot epidural analgesia and unilateral single-injection Transversus Abdominis Plane block in patients undergoing renal surgeries

Public title

The comparison of analgesic effects of epidural and TAP block

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria would be as follows: 1- ASA class I to II
2- Renal surgeries including open nephrectomy, radical nephrectomy, open surgery for renal or ureteral stones.
Exclusion criteria are as follows: 1- Long lasting surgery (more than three hours) 2- Chronic use of opioid 3-

Complications such as severe hemorrhage 4- Intractable nausea and vomiting 5- Two episodes of intractable pain 6- More drug prescriptions other than protocol 7- Difficult airway 8- Drug allergy 9- Diabetes mellitus, Pregnancy, morbid obesity

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Faculty of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Velenjak, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-11-11, 1393/08/20

Ethics committee reference number

308/14549

Health conditions studied

1

Description of health condition studied

Acute post-operative pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

2

Description of health condition studied

nephrectomy

ICD-10 code

Z90.5

ICD-10 code description

acquired absence of kidney

Primary outcomes

1

Description

post operative pain

Timepoint

24 hours after surgery

Method of measurement

VRS(Verbal Rating Scale)

2

Description

opioid use after surgery

Timepoint

24 hours after surgery

Method of measurement

mg

Secondary outcomes

1

Description

Bradypnea (RR <10)

Timepoint

after opioid use

Method of measurement

continuous observation

2

Description

itching

Timepoint

after opioid use

Method of measurement

observation

3

Description

vomiting

Timepoint

after opioid use

Method of measurement

observation

4

Description

hemorrhage during surgery

Timepoint

after intervention,during surgery
Method of measurement
observation (ml)

5

Description
hospital stay
Timepoint
after intervention
Method of measurement
patient file information

Intervention groups

1

Description
Lumbar epidural catheter placement and injection a total volume of 15cc including 4cc bupivacaine 0.5% and 11cc pure water before induction of anesthesia
Category
Prevention

2

Description
perform unilateral TAP block at the site of surgery and injection a total volume of 15cc including 4cc bupivacaine 0.5% and 11cc pure water after induction of anesthesia and 10 minutes before surgical incision
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran
Full name of responsible person
Babak Gharaei
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Department of Anesthesiology, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Anesthesiology Research Center, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran
Full name of responsible person
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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
Anesthesiology Research Center, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran
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
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Person responsible for updating data

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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