Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 sugeries

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/Remifentanil 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

Labbafijejad Hospital, Shahid Beheshti University of Medical Sciences

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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 sugeries

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 sugery

Method of measurement
VRS(Verbal Rating Scale)

2

Description
opioid use after surgery

Timepoint
24 hours after sugery

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 of15cc 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 of15cc 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

Street address

Department of Anesthesiology, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Anesthesiology Research Center, Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

Full name of responsible person

Homayoun Aghamohammadi

Street address

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

City

Tehran

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

Name of organization / entity

Anesthesiology Research Center , Labbafinejad Hospital, 9th Boostan, Pasdaran, Tehran, Iran

Full name of responsible person

Babak Gharaei

Position

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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