

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of Transversus Abdominis Plane Block for Acute Postoperative Pain Relief in Kidney Recipients, a Double Blinded Clinical Trial

Protocol summary

Summary

1) Major eligibility and objectives: Postoperative pain control is a concern after renal transplant and administration of systemic analgesic may be difficult because of underlying co-morbidities, and variable responses of the graft. Our main objective is evaluation the effect of transversus abdominis plane (TAP) block on postoperative pain relief following renal transplantation.

2) Participants: Inclusion criteria: 1) ASA class II and III patients 2) Aged 15–65 year who were scheduled as kidney recipients under general anesthesia Exclusion criteria: 1) Addiction to opioids 2) Long term usage of antidepressants, antipsychotics, anticonvulsants, clonidine 3) Patients with coagulopathy and hepatomegaly. 3) Design, setting and conduct : Forty-four kidney recipients were randomized into two equal groups and were anesthetized with the same technique.

4) Intervention: After the induction of anesthesia, 15 mL of 0.25% Bupivacaine plus 5 µ/ml epinephrine in study group and the same volume of saline in control group was deposited into the transversus abdominis neurofascial plane on the side of surgery by ultrasound guide.

5) Measures and variable criteria: Each patient was assessed by a blinded investigator using NRS at first, 4th, 8th, 12th and 24hr postoperatively. Intraoperative and first 24 hours opioid consumption and demographic data were compared between the study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012185264N3**

Registration date: **2012-09-20, 1391/06/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-20, 1391/06/30

Registrant information

Name

Sussan Soltani Mohammadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-11-01, 1389/08/10

Expected recruitment end date

2011-03-01, 1389/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Transversus Abdominis Plane Block for Acute Postoperative Pain Relief in Kidney Recipients, a Double Blinded Clinical Trial

Public title

Efficacy of Transversus Abdominis Plane Block for Acute Postoperative Pain Relief in Kidney Recipients, a Double Blinded Clinical Trial

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: 1) ASA class II and III patients 2) Aged 15–65 year who were scheduled as kidney recipients under general anesthesia Exclusion criteria: 1)Addiction to opioids 2) Long term usage of antidepressants, antipsychotics, anticonvulsants, clonidine 3) Patients with coagulopathy and hepatomegaly.

Age
 From **15 years** old to **65 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **44**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

1

Registry name
 none

Secondary trial Id
 none

Registration date
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Tehran University of Medical Sciences

Street address
 Poorsiina street,Keshavraz blv

City
 Tehran

Postal code
 14117113135

Approval date
 2010-04-20, 1389/01/31

Ethics committee reference number
 410

Health conditions studied

1

Description of health condition studied
 kidney recipiet,s patients

ICD-10 code
 Z94.0

ICD-10 code description
 kidney transplant status

Primary outcomes

1

Description
 postoperative pain

Timepoint
 at 1st , 4th , 8th , 12th and 24h following surgery

Method of measurement
 numeric rating scale

Secondary outcomes

1

Description
 Intraoperative and first 24 hours opioids consumption

Timepoint
 At the end of operation and end of first 24 hours after operation

Method of measurement
 Dose calculation in mg

Intervention groups

1

Description
 In study group:22 patients were blocked by 15 ml bupivacaine 0.5% + 5 micro-gram/ml epinephrine on the side of surgery and ultrasound guide after induction of anesthesia.The probe was inserted between iliac crest and costal margin behind the midaxillary line.The drug was injected between transverse abdominis neurofascial plane.

Category
 Treatment - Drugs

2

Description
 In control group ,20 ml normal saline was injected in transverse abdominis neurofascial plane under sonography guide after induction of anesthesia at the side of surgery.The probe was inserted between iliac crest and costal margin behind the midaxillary line.

Category
 Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shariati Hospital

Full name of responsible person

Sussan Soltani Mohammadi

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Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research,Tehran University of Medical Sciences

Full name of responsible person

Dr akbar fotoohi

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Poorsina street,Keshvarz blv

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Tehran

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

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

Tehran university of medical sciences

Full name of responsible person

Sussan Soltani Mohammadi

Position

Associated professor

Other areas of specialty/work**Street address**

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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