

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 21 2229 5296

###### Email address

soltanmo@sina.tums.ac.ir

##### 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 recipient,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  
**Street address**  
North kargar street, Ale-ahmad highway  
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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  
**Street address**  
Poorsina street,Keshvarz blv  
**City**  
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**  
North kargar street, Ale-ahmad highway,Dr Shariati

## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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*