Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of subcutaneous infiltration of Dexmedetomidine plus Ropivacaine and Ropivacaine alone in the surgical wound site in reducing pain after kidney surgery with flank incision.

Protocol summary

Study aim

Determining the analgesic effect of dexmedetomidine infiltration in the surgical wound after open kidney surgery

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 2-3 on 60 patients. Computer-generated random table method was used for randomization

Settings and conduct

This double-blind clinical trial will be conducted on 60 male-female patients who are candidates for open renal surgeries with flank incision at Sina Hospital in Tehran. The patients are divided into two groups by Computer-generated random table . This study is double blind clinical trial. Outcome analyser , the outcome evaluator and the participant are blinded (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients candidate for open renal surgery , Patients who consent to participate in the study. Exclusion criteria: History of allergy toRopivacain or Dexmedetimidine , history of drug addiction,or other psychedelic drugs, history of psychological disorder

Intervention groups

Control group: 20 ml of ropivacaine 0.5% is injected under the skin at the edge of the surgical wound before the wound is completely closed. Intervention group, 20 ml of ropivacaine 0.5% plus dexmedetomidin 100 micrograms are injected into the edge of the surgical wound in the subcutaneous area before the wound is completely closed.

Main outcome variables

The total amount of analgesic consumption after surgery,Acute Postoperative Pain, Agitation and Sedation degree, The first time requires analgesia after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N14**
Registration date: **2022-09-04, 1401/06/13**
Registration timing: **prospective**

Last update: **2022-09-04, 1401/06/13**
Update count: **0**

Registration date

2022-09-04, 1401/06/13

Registrant information

Name

mohammadreza khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1220

Email address

khajavim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2023-09-01, 1402/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of subcutaneous infiltration of Dexmedetomidine plus Ropivacaine and Ropivacaine alone in the surgical wound site in reducing pain after kidney surgery with flank incision.

Public title
Comparison of Ropivacaine-Dexmedetomidine infiltration with Ropivacaine at the wound edge in reducing pain after open kidney surgeries.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have the consent to participate in the study Patients who are candidates for open kidney surgery

Exclusion criteria:
History of allergies to the drugs used History of addiction to drugs or other psychotropic substances History of psychological disorder

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For the randomization of patients who meet the inclusion criteria, the method of four blocks including intervention and control groups will be used.The preparation of randomization sequences will be done using the Random Generator software and the created sequences will be given to a trained staff member of the operating room who is not a member of the research group.The researchers of this study will not be aware of the existing sequences and arrangement of the blocks.After the patient enters the operating room, the trained person removes the first sequence from the special box of this study and according to the predetermined protocol, if it is D, it will be transferred to the intervention group, and if it is C, it will be transferred to the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients do not know their group.Eligible participants were assigned to receive either Ropivacaine (group R) or Diphenhydramine as (group D) according to a computer-generated randomization schedule. These medications are prepared in identical syringes and volumes and are identified with the patient name and hospital registration number. At the end of the surgery, these drugs are given to the surgeon for injection, who is blinded to the allocation groups. Another researcher who is blinded to the assigned group will assess the severity of pain in the recovery room and ward.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Sina Hospital ,Tehran University of Medical Sciences

Street address
Sinai Hospital,Imam Khomeini street

City
Tehran

Province
Tehran

Postal code
1136746911

Approval date
2022-06-22, 1401/04/01

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1401.031

Health conditions studied

1

Description of health condition studied
local anesthetic effect of Dexmedetomidine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Total analgesics consumption during the first 24 hr after surgery

Timepoint
One time at the end of the first 24 hours after operation

Method of measurement
According to the patient file and nursing report

2

Description
When was the first need for analgesics

Timepoint
During 6 hours after surgery

Method of measurement

In terms of time per minute, and according to the first time after extubation of patients, the analgesic is injected.

3

Description
Acute Postoperative Pain
Timepoint
In recovery room and 1,6,12,18 and 24 hours after surgery
Method of measurement
Visual Analog Scale(VAS score)

4

Description
Agitation and Sedation degree
Timepoint
In recovery room and 1,6,12,18 and 24 hours after surgery
Method of measurement
Ramsy Sedation Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 20 ml of ROPIVACAINA 0.5%, (made by Molteni company Italia) is prepared with the help of a neurse of anesthesiology according to the patient's grouping, and the surgeon injects it under the skin before completely closing the wound on both sides of the wound edge.After wound closure and endotracheal tube extubation, the patient was transferred to the recovery room, and data about the study variables is collected in the recovery and ward section.If patients have severe pain, morphine (made by Caspian Tamin company) will be used for postoperative analgesia.
Category
Treatment - Drugs

2

Description
Intervention group: 20 ml of ROPIVACAINA 0.5%, (made by Molteni company Italia)along plus100 micrograms of dexmedetomidin (manufactured by Darou Darman Arang factory) is prepared with the help of a neurse of anesthesiology according to the patient's grouping, and the surgeon injects it under the skin before completely closing the wound on both sides of the wound edge.After wound closure and endotracheal tube extubation, the patient was transferred to the recovery room, and data about the study variables is collected in the recovery and ward section.If patients have severe pain, morphine (made by Caspian Tamin company) will be used for postoperative analgesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mohammad Reza Khajavi
Street address
Sina Hospital Imam khomeini st
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8550
Email
khajavim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3686
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Khajavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sina Hospital,Immam Khominie St

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1220

Fax

+98 21 6312 0000

Email

khajavim@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Khajavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sinai Hospital,Imam Khomeini Street

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Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1220

Fax

+98 21 6312 0000

Email

khajavim@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Khajavi

Position

Professor

Latest degree

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Other areas of specialty/work

Anesthesiology

Street address

Sinai Hospital,Imam Khomeini Street

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

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Fax

+98 21 6312 0000

Email

khajavim@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Main study outcome data

When the data will become available and for how long

Six months after the end of the study

To whom data/document is available

University researchers

Under which criteria data/document could be used

Share experiences to increase the knowledge

From where data/document is obtainable

khajavim@tums.ac.ir -Dr.khajavi

What processes are involved for a request to access data/document

The request will be made by email and the answer will be given within two months

Comments