Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Infiltration of Diphenhydramine versus subcutaneous Lidocaine at the wound site to reduce pain after open renal surgeries

Protocol summary

Study aim
Determination of analgesic effect of diphenhydramine injection on the edge of surgical wound after open renal surgery

Design
A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 2-3 on 60 patients. Block randomization 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 Block balanced randomization. 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 to lidocaine or diphenhydramine,History of sleep apnea, history of drug addiction,or other psychedelic drugs,History of acute drug or alcohol intoxication, history of psychological disorder

Intervention groups
Intervention group 10 ml of normal saline containing 10 mg/ml diphenhydramine is injected into the edge of the surgical wound under the skin before the wound is completely closed. control group:10 ml of normal saline containing 10/ml mg lidocaine is injected at the edge of the surgical wound under the skin before the wound is completely closed.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130304012695N13**
Registration date: **2022-07-08, 1401/04/17**
Registration timing: **prospective**

Last update: **2022-07-08, 1401/04/17**
Update count: **0**

Registration date
2022-07-08, 1401/04/17

Registrant information

Name
mohammadreza khajavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6312 1220

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-11, 1401/04/20

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Infiltration of Diphenhydramine versus subcutaneous Lidocaine at the wound site to reduce pain after open renal surgeries

Public title
Comparison of Diphenhydramine injection at wound edge and lidocaine In reducing pain after open kidney surgery
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 sleep Apnea History of addiction to drugs or other psychotropic substances History of acute drug or alcohol poisoning 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
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 4. In each block, 2 individuals will be in intervention group 1 and 2 will be in intervention group 2. A total of 20 blocks will be considered for the study. All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 20 blocks to select 80 people. We randomly select these blocks from 1 to 6. Using the software, we choose a random number between the numbers 1 to 6. For example, if the number 6 is selected as the first block and the number 2 as the second block, the people who enter the study will be given BAABAABB, respectively. Finally, group A receives control intervention and group B receives treatment intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients do not know their group.Eligible participants were assigned to receive either lidocaine (group L) 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
2022-06-01, 1401/03/11
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1401.025

Health conditions studied

1

Description of health condition studied
local anesthetic effect of diphenhydramine
ICD-10 code
ICD-10 code description

Primary outcomes

1

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)

2

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

3

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.

4

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 ml of normal saline, which contains Diphenhydramine (rahapharm company)10 milligrams per milliliter, is prepared with the help of an anesthesiologist 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) will be used for postoperative analgesia.
Category
Treatment - Drugs

2

Description
Control group: 10 ml of normal saline, which contains Lidocaine (made by Caspian Tamin company)10 milligrams per milliliter, is prepared with the help of an anesthesiologist 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.
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1417653761
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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
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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