

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Dexmedetomidin Infusion on Reducing Pain After Open Kidney Surgery

Protocol summary

2018-08-11, 1397/05/20

Study aim

Determination of the Effect of Dexmedetomidine on Pain After Open Surgery of Kidney Stones

Design

In this double-blind study, 33 patients who will be candidated for renal surgery in a randomized, randomized manner were randomly assigned to two groups of control and intervention.

Settings and conduct

This study will be conducted at Mashhad University of Medical Sciences, Imam Reza Hospital and Ghaem Hospital. In this study, researchers and patients are not aware with the type of interior.

Participants/Inclusion and exclusion criteria

After approving of the Ethical Committee of the Mashhad University of Medical Sciences and consent form of patients in Imam Reza and Ghaem Hospital, patients who are candidates for open surgery of renal kidney will be included in the study.

Intervention groups

1. Intervention group: Slow infusion of 200 micrograms of dexmedetomidine 2. Control group: Slow infusion of normal saline in intravenous

Main outcome variables

Postoperative pain level based on VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170429033680N8**

Registration date: **2018-08-11, 1397/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-11, 1397/05/20**

Update count: **0**

Registration date

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2631

Email address

golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Dexmedetomidin Infusion on Reducing Pain After Open Kidney Surgery

Public title

Dexmedetomidin Infusion on Reducing Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for open-renal surgery consenting to participate in the study age 18-65 years ASA class 1 and 2 BMI more than 30 have not allergy to the drug no

addiction to drug or alcohol not taking benzodiazepines permanently Exclusion criteria: Systolic blood pressure lower than 100 heart rate less than 60 before the injection Hypotension or heart rate decrease by more than 30% at baseline or during the injection History of psychological illness Use of any analgesic drug before operation Needing to use an additional dose of opiates of more than 20% of the standardized value in the study during anesthesia Be longer surgery for any reason failure to do or complete the surgery at any stage for any reason	Ethics committee of Mashhad University of Medical sciences Street address Mashhad University of Medical Sciences; International Offic Administration Center(Qoreishi Building) ; Daneshgah St., Mashhad Mashhad City Mashhad Province Razavi Khorasan Postal code 9137913316
Age From 18 years old to 65 years old Gender Both Phase N/A Groups that have been masked • Participant • Investigator	Approval date 2018-06-22, 1397/04/01 Ethics committee reference number IR.MUMS.fm.REC.1397.15
Sample size Target sample size: 33 Randomization (investigator's opinion) Randomized Randomization description The envelope method is that the envelopes are prepared and printed by a member of the research team and random numbers with the help of the Randomaize.com site and inside the envelope. The door packs will be closed and its contents are not visible from the outside. Then, the purpose of the study is explained to the person who described the conditions, and the person, if desired, signs the informed consent form and removes an envelope, then opens it and, based on the contents of the envelope, enters into the intervention or control group. Blinding (investigator's opinion) Double blinded Blinding description Participants and researcher are not aware of the type of intervention.The trial was planned in such a way that neither the subjects nor the observers (researchers) know who the group is. Placebo Used Assignment Parallel Other design features	Health conditions studied <u>1</u> Description of health condition studied Kidney surgery ICD-10 code N18 ICD-10 code description Chronic kidney disease (CKD) Primary outcomes <u>1</u> Description Analgesia Timepoint after surgery Method of measurement VAS scale Secondary outcomes empty Intervention groups <u>1</u> Description Intervention group: Infusion of a dose of 200 micrograms (2 cc) of dexmedmodine was done ones before surgery. Category Treatment - Drugs
Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee	<u>2</u> Description Control group: infusion of 50 cc normal salinewas done ones before surgery Category Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mohsen Saber Moghadam Ranjbar

Street address

Imam Reza Hospital, Taghiabad Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, International
Office Administration Center(Qoreishi Building),
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice chancellor for research, Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Saber Moghadam Ranjbar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Department of Anesthesiology, Imam Reza (AS)
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Saber Moghadam Ranjbar

Position

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Person responsible for updating data

Contact**Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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