

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the preventive effect of intravenous diphenhydramine injection before induction of anesthesia on control of the catheter bladder discomfort after Nephrolithiasis surgery

Protocol summary

Study aim

Reduce pain and catheter bladder discomfort in patients after surgery and increase their cooperation in recovery and ward

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 2 on 70 patients. The software rand function was used to randomize.

Settings and conduct

patients who are candidates for PCNL surgery in Sina hospital in the operating room with the Computer Generated Table technique are divided into two groups: Diphenhydramine (D) and Placebo (P). Before induction of anesthesia Diphenhydramine 0.6 mg / kg (maximum 50 mg) diluted in 5cc syringe (1cc = 10mg) is injected intravenously (IV) and in the placebo group, the same volume of 5 cc normal saline is injected. Anesthesia is the same in both groups. Before incision, all patients receive 0.1 mg / kg morphine sulfate slowly intravenously within two minutes. The degree of sedation based on the Ramsy sedation scale, hemodynamic changes during extubation, severity of pain based on (visual analog scale) and the incidence and severity of bladder discomfort will be evaluated in recovery. The need for analgesia in recovery and 24 hours after surgery is also assessed and recorded. Paracetamol is used for postoperative analgesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients candidate for per cutaneous nephrolithotomy (PCNL) Exclusion criteria: Glucome, benign prostate hypertrophy, opioids addiction

Intervention groups

Intervention group: 50 mg of diphenhydramine is injected intravenously before anesthesia and the degree of agitation, pain during extubation and feeling of urination and severity of catheter bladder discomfort in recovery and ward will be evaluated Control group: They

do not receive medication

Main outcome variables

Incidence and severity of catheter bladder discomfort
degree of sedation thermodynamics changes analgesic requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N7**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-21, 1399/04/31**

Update count: **0**

Registration date

2020-07-21, 1399/04/31

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

2019-08-23, 1398/06/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the preventive effect of intravenous diphenhydramine injection before induction of anesthesia on control of the catheter bladder discomfort after Nephrolithiasis surgery

Public title

control catheter bladder discomfort

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All candidate candidate patients for Nephrolithiasis surgery

Exclusion criteria:

history of large prostate disease Glucome Drug addiction uncontrolled hypertension

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize patients with inclusion criteria Block balanced randomization is used. Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants. Those who evaluate the outcome. Data collection officials.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Sina Hospital, Imam Khomeini st.

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.286

Health conditions studied**1****Description of health condition studied**

catheter bladder discomfort

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes**1****Description**

Incidence and severity of catheter bladder discomfort

Timepoint

During extubation and 5, 15, 30 and 60 minutes after surgery

Method of measurement

Visual Analogue Scale

2**Description**

Severity of postoperative agitation

Timepoint

During extubation and 5, 15, 30 and 60 minutes after surgery

Method of measurement

Ramsy sedation Scale

3**Description**

Analgesic requirement in recovery and ward

Timepoint

During recovery period and first 24 hours after surgery

Method of measurement

The total amount of mg of morphine consumed

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 mg of diphenhydramine is injected intravenously before anesthesia and the degree of agitation, pain, and hemodynamic changes during extubation, and the incidence and severity of catheter bladder discomfort in the recovery and the total amount of analgesic requirement are evaluated during 24 hours after surgery.

Category

Prevention

2

Description

Control group: They do not receive medication and the degree of agitation, pain, and hemodynamic changes during extubation, and the incidence and severity of catheter bladder discomfort in the recovery and the total amount of analgesic requirement are evaluated during 24 hours after surgery.

Category

Prevention

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

Mohammad Ali Sahraeian

Street address

Keshavarz Blvd., corner of Quds St., Central
Organizatioehran University of Medical Sciencesn of T

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

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 Imam Khomeini st

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8550

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

Mohammad Reza Khajavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sina Hospital Imam Khomeini st

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8550

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

Mohammad Reza Khajavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sina Hospital Imam Khomeini st

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8551

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

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information used for this research can be shared after unidentified the identity of patients. Also, statistical information, information analysis, study method, findings and conclusions can be shared.

When the data will become available and for how long

Starting access after accepting by a valid scientific journal and publishing it

To whom data/document is available

For academic researchers and in the field of science

Under which criteria data/document could be used

All researchers can use all published material and if all or part of this research is published by other people, the name and source of this research and its researchers should be mentioned.

From where data/document is obtainable

Mohammad Reza Khajavi khajavim@tums.ac.ir

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

The applicant can request the type of files by email.

Comments