

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effects of intravenous infusion of lidocaine on the sedation of patient after percutaneous nephrolithotomy surgery

Protocol summary

Summary

Objective: To assess the effect of intravenous infusion of lidocaine in the comfort of the patient in the recovery room after surgery, PCNL Design: Randomized, double-blind, single-center, phase II clinical trial. Performance: Group of intravenous lidocaine infusion to the patient mg / kg / h 1.5 until the end of the operation received an IV infusion. The control group received lidocaine infusion. Inclusion criteria included: patients ASA1 (without any medical conditions or mental), age between 20 years to 60 years. Exclusion criteria included: age less than 20 years and more than 60 years, ASAII and higher sensitivity to lidocaine, kidney surgery, drug addiction, dependence on various drugs. Interventions: The first group of mg / kg / h 1.5 until the end of the operation received an IV infusion, the second group received lidocaine infusion. The main outcome variables: quality of sedation is intravenous infusion of lidocaine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011732017N1**

Registration date: **2017-03-24, 1396/01/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-24, 1396/01/04

Registrant information

Name

Mahmoud Reza Mohaghegh Dolat Abadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 140 6348

Email address

mohaghegh.mr@moheb.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of intravenous infusion of lidocaine on the sedation of patient after percutaneous nephrolithotomy surgery

Public title

Effects of intravenous infusion of lidocaine in the sedation of patient in recovery after percutaneous nephrolithotomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: Patients under percutaneous nephrolithotomy surgery. Exclusion criteria included: Age less than 20 years and more than 60 years; ASAII and higher; sensitivity to lidocaine and kidney surgery.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Postal code

Approval date
2015-07-04, 1394/04/13

Ethics committee reference number
IR.IUMS.rec.1394.921117418

Health conditions studied

1

Description of health condition studied
Urinary stone

ICD-10 code
N21.0

ICD-10 code description
Urinary bladder stone

Primary outcomes

1

Description
Quality of sedation

Timepoint
After treatment

Method of measurement
Based on Richmond Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients received an lidocaine IV infusion 1.5 mg/kg /h until the end of the operation.

Category
Treatment - Drugs

2

Description
Control group: Patients not received an lidocaine IV infusion.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hashemi Nejad Hospital

Full name of responsible person
Dr. Mahmudreza Mohaghegh

Street address
Vali nezhad Ave, Hashemi Nejad Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person
Dr Morteza Naserbakht

Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

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, Iran 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*Central staff, Iran University of Medical Sciences,
Hemmat Highway**City**

Tehran

Postal code**Phone**

+98 912 298 9628

Fax**Email**

Mohaghegh.mr@moheb.com

Web page address**Person responsible for updating data****Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahmudreza Mohaghegh

PositionPh.D., Assistant Professor of Iran University of Medical
Sciences**Other areas of specialty/work****Street address**Central staff, Iran University of Medical Sciences,
Hemmat Highway**City**

Tehran

Postal code**Phone**

+98 912 298 9628

Fax**Email**

Mohaghegh.mr@moheb.com

Web page address**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahmudreza Mohaghegh

Position**Other areas of specialty/work****Street address**Central staff, Iran University of Medical Sciences,
Hemmat Highway**City**

Tehran

Postal code**Phone**

00

Fax**Email**

Mohaghegh.mr@moheb.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahmudreza Mohaghegh

Position

PhD

Other areas of specialty/work**Street address****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*