Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

To evaluate the effect of bupivacaine injection around nephrostomy tract on reduction of post operative pain after percutaneous nephrolithotomy

Protocol summary

Summary

46 adult patients with renal stones who are candidate for single access subcostal percutaneous nephrolithotomy at Ahvaz Imam Khomeini hospital by a single surgeon will be included. Patients will randomly allocate through a computer generated randomization, in a double blinded fashion to bupivacaine treatment group (Intervention group), and saline infiltration group (Control group). All percutaneous nephrolithotomies will be done in a standard aseptic manner and in the prone position under general anesthesia. A 20 F nephrostomy catheter will be left in place after the operations. In the intervention group under fluoroscopic guidance a 23 gauge spinal needle will be introduced along the nephrostomy catheter to the two-thirds of the puncture depth and 15 cc bupivacaine 0.25% will be injected. Afterwards 10 ml drug will be infiltrated around the nephrostomy catheter subcutaneously. Finally the skin will be infiltrated with 5 cc bupivacaine. In control group normal saline will be infiltrated with the same technique. Postoperative pain scores will be collected using a 10 cm self-assessed visual analog scale with 0 being no pain and 10 being the worst pain experienced by the patient. Pain status and analgesic used will be evaluated at 0, 2, 4, 6, 8 and 24 hours. The visual analog scale scores and total dose of analgesics of the two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112122168N3**
Registration date: **2015-12-02, 1394/09/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

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Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Research Vice-Chancellor, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effect of bupivacaine injection around nephrostomy tract on reduction of post operative pain after percutaneous nephrolithotomy

Public title

bupivacaine effect to reduce postoperative pain after percutaneous nephrolithotomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with kidney stone who are candidate for after percutaneous nephrolithotomy and in age range of 18 to 60 years old. Exclusion criteria: cardiovascular disease; Bupivacaine hypersensitivity; renal or skeletal anomalies.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **46**

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 Ahvaz Jundishapur University of Medical Sciences

Street address

ground floor, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd.

City

Ahvaz

Postal code

1579461357

Approval date

2015-05-28, 1394/03/07

Ethics committee reference number

IR.AJUMS.REC.1394.367

Health conditions studied

1

Description of health condition studied

Nephrolithiasis

ICD-10 code

N20.0

ICD-10 code description

Nephrolithiasis

Primary outcomes

1

Description

Amount of pain

Timepoint

At 0, 2, 4, 6, 8 and 24 hours after the surgery

Method of measurement

Based on pain visual analog scale which is filled by the patient from 0 to 10

2

Description

The amount of pethidine used

Timepoint

At 0, 2, 4, 6, 8 and 25 hours after the surgery

Method of measurement

The amount of used drug in miligram

Secondary outcomes

1

Description

Side effects

Timepoint

24 hours after the surgery

Method of measurement

Any changes in blood pressure and cardiac arrhythmias

Intervention groups

1

Description

Intervention group: at the end of percutaneous nephrolithotomy, 30 cc of 0.25% bupivacaine will be injected around the nephrostomy tube

Category

Treatment - Drugs

2

Description

control group: at the end of percutaneous nephrolithotomy, 30 cc of normal saline will be injected around the nephrostomy tube

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Dinyar Khazaeli

Street address

Azadegan Avenue
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research and tech, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Nader Saki
Street address
Office of Vice-chancellor of research and technology, ground floor, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd.
City
Ahvaz
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 and tech, Ahvaz Jundishapur 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

Person responsible for general inquiries

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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