

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Efficacy of Peritubal Local Anesthetic Infiltration in Alleviating postoperative pain in percutaneous Nephrolithotomy

Protocol summary

Summary

Sixty ASA grade I & II patients, 12 to 75 years of age, of either sex were randomized to receive 20 ml of 0.25% bupivacaine (group case) or not (group control) through 23-gauge spinal needle along the nephrostomy tube under fluoroscopic guidance at the end of the surgery. Postoperative pain score was assessed by NRS (Numerical Rating Scale). All patients were informed about the possibility of experiencing short periods of discomfort or pain and completed NRS questionnaires during the intra-operation and at 6, 12, and 24 h postoperatively. Time to first demand analgesia and total dose of narcotic in first 24 hours was noted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210235521N2**

Registration date: **2013-05-05, 1392/02/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-05, 1392/02/15

Registrant information

Name

shahriar amirhassani

Name of organization / entity

hamadan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 812 7721

Email address

amirhassani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2011-12-21, 1390/09/30

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Peritubal Local Anesthetic Infiltration in Alleviating postoperative pain in percutaneous Nephrolithotomy

Public title

Decreasing pain after PCNL

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: the patient with any size of renal stone that refer to Beheshti hospital, Hamadan, Iran for renal stone treatment and is candidate for PCNL and being volunteer to participate in our study. Exclusion criteria: having more than 2 nephrostomy tube; having significant hematuria; having any residual stone after surgery; having any contraindication for PCNL and do not be volunteer.

Age

No age limit

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
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences Ethics Committee

Street address

Hamedan University of Medical Sciences

City

Hamedan

Postal code

Approval date

2011-10-02, 1390/07/10

Ethics committee reference number

1101/9/35/16/P/D

Health conditions studied

1

Description of health condition studied

kidney calculi

ICD-10 code

N20-N23

ICD-10 code description

Calculus of kidney and ureter, Unspecified renal colic

Primary outcomes

1

Description

Pain after PCNL

Timepoint

Recovery, 6, 12, 24 hours after surgery

Method of measurement

Numerical rating scale

Secondary outcomes

1

Description

The first need of analgesic

Timepoint

The first 24 r after surgery

Method of measurement

Interval of surgery end and the first need of analgesic (hours)

2

Description

Dose of analgesic in first 24 hours post operation period

Timepoint

First 24 hours post operation period

Method of measurement

Dose of analgesic (mg)

Intervention groups

1

Description

Intervention group: receive 20 ml of 0.25% bupivacaine around nephrostomy tube from capsule to skin after surgery

Category

Other

2

Description

Control group: no Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Shahriar Amirhassani

Street address

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Hamadan University of Medical Sciences

Full name of responsible person

Haidar Tavalani

Street address

Hamadan University of Medical Sciences, Fahmideh

blvd
City
Hamadan
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 technology, Hamadan 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

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Shahriar Amirhassani
Position
urologist/attend
Other areas of specialty/work
Street address
Urology department, Beheshti hospital, Eram blvd
City
Hamadan
Postal code
Phone
+98 81 1838 0703
Fax
Email
amirhassani@umsha.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person

Dr Shahriar Amirhassani
Position
Urologist
Other areas of specialty/work
Street address
Shahid Beheshti Hospital
City
Hamadan
Postal code
Phone
+98 81 1838 0703
Fax
Email
amirhassani@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Dr Shahriar Amirhassani
Position
Urologist/attend
Other areas of specialty/work
Street address
Urology department, Beheshti hospital, Eram blvd
City
Hamadan
Postal code
Phone
Fax
Email
Web page 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