

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of Ropivacaine on post-operative pain after Transcataneous Percataneous Nepholytotomy

Protocol summary

Summary

The purpose of study is evaluation of effect of Ropivacaine on post-operative pain, opium need and respiratory changes after "Percutaneous Nephrolitotomy operation". Inclusion criteria: Age: 15-60 years, weight less than 40kg. Exclusion criteria: Too many kidney stones which Ropivacaine administration reaches over dosage, retained Kidney stone after operation. 60 patients scheduled for "Percutaneous Nephrolitotomy" at the end of surgery 30 ml Ropivacaine will be injected to the study group. Control group will be received the same amount and manner Isotonic Saline. After 4 and 6 hour of the surgery, pain score and peak expiratory flow rate of the patients will be measured. The amount of analgesic during 6 hour will be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307153773N8**

Registration date: **2015-01-15, 1393/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-15, 1393/10/25

Registrant information

Name

Farsad Imani

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ropivacaine on post-operative pain after Transcataneous Percataneous Nepholytotomy

Public title

The effect of Ropivacaine on post-operative pain after Transcataneous Percataneous Nepholytotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age:15-60 y; Weight less than 40kg; Percataneous Nepholytotomy operation. Exclusion criteria: Too many kidney stones which Ropivacaine administration reaches over dosage; Retained Kidney stone after operation.

Age

From **15 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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavrs Blv. Ghods St. Cross

City

Tehran

Postal code

Approval date

2014-12-14, 1393/09/23

Ethics committee reference number

9011174017-125187

Health conditions studied

1

Description of health condition studied

Pain after Percutaneous Nephrolithotomy

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

pain

Timepoint

4 and 6 h after operation

Method of measurement

VAS (Visual analogue scale)

2

Description

Peak End Expiratory Flow Rate

Timepoint

Before operation/6&4 hour after operation

Method of measurement

Blowing at Peak Flow Meter

Secondary outcomes

1

Description

Peak expiratory flow rate

Timepoint

4 & 6 h after operation

Method of measurement

Ambulatory PEFmeter

Intervention groups

1

Description

At the end of the operation, patients of intervention group, 30 mL of 0. 2% ropivacaine will be instilled into the renal puncture site, nephrostomy tract, and skin. Postoperatively, patients received Apotel I.V. (Acetaminophen) 1g. Pain visual analog score (VAS), peak expiratory flow rate (PEF) will be measured at 4, 6 hours postoperatively. The number of analgesic doses required will be recorded.

Category

Treatment - Drugs

2

Description

At the end of the operation, patients of control group, 30 mL of saline will be instilled into the renal puncture site, nephrostomy tract, and skin. Postoperatively, patients received Apotel I.V. (Acetaminophen) 1g. Pain visual analog score (VAS), peak expiratory flow rate (PEF) will be measured at 4, 6 hours postoperatively. The number of analgesic doses required will be recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Farsad Imani

Street address

Imam Khomeini St. Hasanabad Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Department of Environmental Health Engineering,
School of Public Health, Tehran University of Medical
Sciences

City

Tehran

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

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

Tehran University of Medical Sciences

Full name of responsible person

Farsad Imani M.D.

Position

Assitant Professore

Other areas of specialty/work

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Person responsible for scientific inquiries

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Associated Professore

Other areas of specialty/work

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Position

Anesthesiologist

Other areas of specialty/work

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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