

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of tolterodine and gabapentin in reducing pain and discomfort of catheter after Percutaneous nephrolithotomy surgery at Hashemi Nejad Hospital

Protocol summary

Summary

In this study, we will analyse the effect of Tolterodine and Gabapentin in reducing pain and discomfort of catheter after Percutaneous nephrolithotomy surgery. 100 patients of PCNL surgery candidate are included. After recording of their demographic data and past medical history into checklists, they divided to three groups with balance blocked randomization. First group are getting placebo, second and third group are getting Gabapentin and Tolterodine. The placebo group includes people who feel discomfort after PCNL in the lumen of the catheter after extubation are taking opioid analgesic drug 25 mg per injection. Group 1 consists of people who are taken Tolterodine 2mg orally 1 hour before surgery and Group 2 are taken Gabapentin 600mg (2 capsules Gabapentin 300mg) 1 hour before the surgery. Then, 1, 3, 6, 12 and 24 hours after extubation and at the time of requesting rescue drug, the pain of people are recorded by VAS score (visual analog scale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204066504N3**
Registration date: **2016-12-07, 1395/09/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

Robab Maghsoudi

Name of organization / entity

Iran University of Medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University Of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of tolterodine and gabapentin in reducing pain and discomfort of catheter after Percutaneous nephrolithotomy surgery at Hashemi Nejad Hospital

Public title

The effect of tolterodine and gabapentin in reducing pain and discomfort after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCNL surgery candidate; Older than 18 years old; Risk of anesthesia was ASA 1 Exclusion criteria: Alcohol or drug abuse; Sensitivity to gabapentin, tolterodine or opioids; Using opioids 12 hour

before surgery; Any confounding medical or psychological situation of patients

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

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences ,hemmat
expresway, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-05-24, 1395/03/04

Ethics committee reference number

IR.IUMS.REC1395.9221254002

Health conditions studied

1

Description of health condition studied

Nephrolithiasis

ICD-10 code

N22.8

ICD-10 code description

Calculus of urinary tract in other diseases classified elsewhere

Primary outcomes

1

Description

Pain of cathetring

Timepoint

1,3,6,12 and 24 hours after PCNL surgery

Method of measurement

Visual analouge scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The placebo group includes people who feel discomfort after PCNL in the lumen of the catheter after extubation are taking opioid analgesic drug 25 mg per injection.

Category

Placebo

2

Description

Intervention: Group 1 consists of people who are taken tolterodine 2mg orally 1 hour before surgery with a little water.

Category

Treatment - Drugs

3

Description

Intervention: Group 2 are taken Gabapentin 600mg (2 capsules Gabapentin 300mg) 1 hour before the surgery. Also, all the people who feel pain and discomfort during the study was prescribed analgesic 25mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hashemi Nejad Hospital

Full name of responsible person

Dr. Saeed Farhadi Niaki

Street address

no 34, Shahid Hashemi Nejad Hospital, Valinejad
Avn.,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Pejman Shadpour

Street address

no 39, Hashemi Nejad Hospital, Valinejad Avn., Vanak square, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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

Person responsible for general inquiries

Contact**Name of organization / entity**

Faculty of medicine

Full name of responsible person

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Position

Resident

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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