

# 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

Iran (Islamic Republic of)

###### Phone

+98 21 8864 4486

###### Email address

robab.maghsoudi@hkc.ir

##### 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

Dr. Saeed Farhadi Niaki

#### Position

Resident

#### Other areas of specialty/work

#### Street address

Shahid Hashemi Nejad Hospital

#### City

Tehran

#### Postal code

#### Phone

+91 11270765

#### Fax

#### Email

saeed.niaki@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

### Name of organization / entity

Faculty of medicine

### Full name of responsible person

Dr. Robabe Maghsoudi

### Position

Assistant professor

### Other areas of specialty/work

### Street address

Shahid Hashemi Nejad Hospital

### City

Tehran

### Postal code

### Phone

+98 914 411 0966

### Fax

### Email

rmaghsudy@yahoo.com

### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Iran University Of Medical Sciences

#### Full name of responsible person

Dr. Saeed Farhadi Niaki

#### Position

Resident

#### Other areas of specialty/work

#### Street address

Shahid Hasheminejad Hospital, Valinejad Avn., Vanak square, Tehran, Iran

#### City

Tehran

#### Postal code

#### Phone

+98 218116250

#### 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