

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison the efficacy of Tramadol and Diclofenac in the treatment of renal colic.

#### Protocol summary

##### Summary

Methods:Aim of double-blind randomized clinical trial are compared the efficacy of tramadol and diclofenac in the tretment of renal colic.In this study 150 patients with acute renal colic will assessed.The patients devide to 3 groups randomly.The first group give 50mg tramadol (IM),Second group receive 75mg diclofenac (IM) AND The third group(control)give 50 mg pethidine (IV).The pain severity will assessed before and then at 15,30,60 minute after drugs administration,on the base of MacGill questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105293912N3**  
Registration date: **2012-01-15, 1390/10/25**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-01-15, 1390/10/25

##### Registrant information

##### Name

Kobra Nourian

##### Name of organization / entity

Sharekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1333 5648

##### Email address

noorian@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrekord University of Medical Sciences

##### Expected recruitment start date

2012-01-21, 1390/11/01

##### Expected recruitment end date

2012-05-21, 1391/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the efficacy of Tramadol and Diclofenac in the treatment of renal colic.

##### Public title

Comparison the efficacy of Tramadol and Diclofenac in the treatment of renal colic.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria :Patients with acute renal colic thats confirm with IVP,KUB.CT-Scan,Sonography.age between 15-65 years Exclusion Criteria,pregnancy.asthma,allery ,hemorrhagic diseases,drug abuses.

##### Age

From **15 years** old to **65 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **150**

##### 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**

Shahrekord University of Medical Sciences

**Street address**

Shahrekord - kashani-Street

**City**

Shahrekord

**Postal code****Approval date**

2009-06-26, 1388/04/05

**Ethics committee reference number**

810

**Health conditions studied****1****Description of health condition studied**

Renal colic

**ICD-10 code**

n20-n23

**ICD-10 code description**

Urolithiasis

**Primary outcomes****1****Description**

pain

**Timepoint**

The pain severity will assessed before and then at 15,30,60 minute after drugs administration.

**Method of measurement**

MacGill questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

50mg pethedin iv(control group)

**Category**

Treatment - Drugs

**2****Description**

75mg Diclofenac(IM)

**Category**

Treatment - Drugs

**3****Description**

50mg Tramadol(IM)

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kashani Hospital

**Full name of responsible person**

Kobra Noorian

**Street address**

Parastar Street

**City**

Shahrekord

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Saadat Maryam

**Street address**

Kashani Street

**City**

Shahrekord

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

Yes

**Title of funding source**

Shahrekord 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**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Noorian Kobra

**Position**

Lecturer

**Other areas of specialty/work**

**Street address**

Kashni Street

**City**

Shahrekord

**Postal code**

**Phone**

+98 38 1333 5648

**Fax**

**Email**

noorian@skums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Rajae Mohammad Ali

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Kashani Street

**City**

Shahrekord

**Postal code**

**Phone**

+98 38 1226 4826

**Fax**

**Email**

m\_rajae@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Noorian Kobra

**Position**

Lecturer

**Other areas of specialty/work**

**Street address**

Kashani Street

**City**

Shahrekord

**Postal code**

**Phone**

+98 38 1333 5648

**Fax**

**Email**

noorian@skums.ac.ir

**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