

# 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**

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## Person responsible for scientific inquiries

### Contact

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Assistant professor

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## Person responsible for updating data

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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*