

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of the effect of ibuprofen injection compared to ketorolac injection in improving renal colic pain of out patients after entering the emergency department

#### Protocol summary

##### Study aim

Evaluation of the effect of ibuprofen injection compared to ketorolac injection in improving renal colic pain

##### Design

A parallel-group, double-blind, randomized, phase 3 clinical trial on 100 patients. Random number generation program will be used for randomization.

##### Settings and conduct

This clinical trial study will be conducted in Golestan Hospital in Ahvaz on patients diagnosed with renal colic. Patients are divided into two groups receiving intravenous ibuprofen or ketorolac, and the pain level is measured at 0, 20, 40, and 60 minutes later.

##### Participants/Inclusion and exclusion criteria

This study will be conducted on acute renal colic pain caused by kidney stones. The entry criteria include urinalysis test (U/A), ultrasound observation based on the presence of mild and moderate hydronephrosis and a history of similar symptoms, rejection of other differential ultrasound diagnoses, and informed consent and the non-entry criteria includes patients who are candidates for surgical intervention and patients with large stone size.

##### Intervention groups

The first group received a dose of 800 mg of intravenous ibuprofen in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40, and 60 minutes after the injection. The second group received a dose of 30 mg of intravenous ketorolac in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40 and 60 minutes after the injection.

##### Main outcome variables

pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230726058930N1**

Registration date: **2023-10-18, 1402/07/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-18, 1402/07/26**

Update count: **0**

##### Registration date

2023-10-18, 1402/07/26

##### Registrant information

###### Name

Ali Vefagh Nematollahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3367 5436

###### Email address

vefagh.a@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2025-03-19, 1403/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of ibuprofen injection compared

to ketorolac injection in improving renal colic pain of out patients after entering the emergency department

**Public title**

Ibuprofen compared to ketorolac in improving renal colic pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients referred to the emergency center with acute renal colic pain caused by kidney stones Diagnosis of renal colic by an emergency medicine specialist considering clinical examination, urinalysis test (U/A), ultrasound based on the presence of mild and moderate hydronephrosis and rule out other differential diagnoses

**Exclusion criteria:**

Patients with coagulation disorders chronic kidney disease (CKD) severe hydronephrosis active gastrointestinal bleeding (GIB) patients who do not respond to treatment up to 30 minutes after drug injection patients who are candidates for surgical intervention patients with large stone size

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly assigned to two intervention groups using randomized block method. For this purpose, blocks of four are prepared and the name of the first intervention is written on two sheets and the name of the second intervention is written on the other two sheets. The sheets are piled up and placed in the container, and one sheet is pulled out for each patient without placing it. Then four sheets are returned to the container and this process is repeated until the sample volume is reached.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz University of Medical Sciences

**Street address**

Emergency Medicine Department Office- Golestan Hospital- Golestan (Farvardin St.)- Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794 - 61357

**Approval date**

2023-07-17, 1402/04/26

**Ethics committee reference number**

IR.AJUMS.REC.1402.242

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

Renal colic

**ICD-10 code**

N23

**ICD-10 code description**

Unspecified renal colic

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

pain

**Timepoint**

0, 20, 40, 60 minutes after injection

**Method of measurement**

Numeric Pain Rating Scale (NRS)

**Secondary outcomes****1****Description**

blood pressure

**Timepoint**

After injection of painkillers

**Method of measurement**

Blood pressure measuring device

**2****Description**

Shortness of breath

**Timepoint**

After injection of painkillers

**Method of measurement**

Borg shortness of breath scale

### 3

**Description**

heart beat

**Timepoint**

After injection of painkillers

**Method of measurement**

Using a sphygmomanometer

### 4

**Description**

nausea

**Timepoint**

After injection of painkillers

**Method of measurement**

Ask the patient

## Intervention groups

### 1

**Description**

Intervention group: The first group received a dose of 800 mg of intravenous ibuprofen in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40, and 60 minutes after the injection.

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: The second group received a dose of 30 mg of intravenous ketorolac in 250 cc of normal saline within 5 minutes to determine the pain intensity at 0, 20, 40 and 60 minutes after the injection.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Imam Khomeyni Hospital

**Full name of responsible person**

Ali Vefagh Nematollahi

**Street address**

Imam Khomeini Medical Education Center Ahvaz-  
Azadegan St.- Ahvaz

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**Province**

Khouzestan

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15794 - 61357

**Phone**

+98 61 3374 3099

**Email**

vefagh.a@ajums.ac.ir

### 2

**Recruitment center****Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Ali Vefagh Nematollahi

**Street address**

Emergency Medicine Department Office- Golestan  
Hospital- Golestan (Farvardin St.)- Ahvaz

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Vefagh nematollahi

**Street address**

Emergency Medicine Department Office- Golestan  
Hospital- Golestan (Farvardin St.)- Ahvaz

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**Province**

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**Phone**

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**Email**

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

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Vefagh nematollahi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Vefagh nematollahi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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**Phone**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Vefagh nematollahi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794 - 61357

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available