

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparative study of controlling the pain in patients that present to ED with renal colic with intravenous ketofol and intravenous morphin sulfate after reciving standard treatment

#### Protocol summary

##### Study aim

Replacment of treatment of renal colic patients with ketofol instead of morphine sulfate

##### Design

A clinical trial with a control group and a parallel group that was randomized in two-way blind and phase 3 was performed on 86 patients and randomized Excel function will be used for randomization.

##### Settings and conduct

Patients with renal colic who refer to the emergency department of Ayatollah Mousavi Hospital in Zanjan between 1400/04/15 and 1400/06/15 and have the conditions and desire to enter our plan using the randomization method and the method There will be two blind strains in which the patient and resident are kept blind to the type of injectable drug.

##### Participants/Inclusion and exclusion criteria

Patients with definitive diagnosis of renal colic with a desire to participate in the study and a minimum of 16 years and a maximum of 60 years of both sexes without having an underlying disease and addiction and history of allergies.

##### Intervention groups

Patients with renal colic who are included in the study are divided into two groups and in the intervention group ketofol at a dose of 0.75 mg / kg body weight is injected intravenously and in the control group morphine sulfate at a dose of 0.1 Mg / kg body weight is injected intravenously.

##### Main outcome variables

Level of controlling the pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210327050778N1**

Registration date: **2021-07-23, 1400/05/01**

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

Last update: **2021-07-23, 1400/05/01**

Update count: **0**

##### Registration date

2021-07-23, 1400/05/01

##### Registrant information

###### Name

Hossein Rahmani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24 3355 0591

###### Email address

drhosseinrahmani01@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-06, 1400/04/15

##### Expected recruitment end date

2021-10-07, 1400/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of controlling the pain in patients that present to ED with renal colic with intravenous ketofol and intravenous morphin sulfate after reciving standard

treatment

### Public title

Comparison of ketofol and intravenous morphin sulfate in controlling the pain in renal colic

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients presenting with back and side pain and hematuria who have a definitive diagnosis of renal colic using physical examination, laboratory tests and radiologic measures such as ultrasonography and abdomino-pelvic CT Age between 16 to 60 years Willingness to participate in the study No history of underlying disease, allergies or addiction

#### Exclusion criteria:

Renal colic patients with any sort of known drug addiction Renal colic patients aged under 16 or over 60 Renal colic patients with underlying illness Renal colic patients with any history of allergy Pregnant patients

### Age

From **16 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **86**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization is performed based on the Randomised software of Excel program in the patients included in the plan and individually

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, which is two-way blind, the people involved in the project include renal colic patient and resident performing clinical trial and supervisor and statistical consultant and drug injecting nurse. Due to the two-way blindness of patient and resident study. They are unaware of the type of drug received by the patient and are kept blind. Thus, we have two classes of drugs, including morphine sulfate and vectofol Is ignorant.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

##### Street address

No.1, Mahdavi Blvd., Karmandan Town

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956184

#### Approval date

2020-09-17, 1399/06/27

#### Ethics committee reference number

IR.ZUMS.REC.1399.230

## Health conditions studied

### 1

#### Description of health condition studied

Renal Colic

#### ICD-10 code

N20.2

#### ICD-10 code description

Calculus of kidney with calculus of ureter

## Primary outcomes

### 1

#### Description

Level of controlling the pain

#### Timepoint

10, 30, 60, and 120 minute after intervention

#### Method of measurement

Visual analogue scale system

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The second group, which is also called the intervention group in this trial, is injected intravenously with ketofol at a dose of 75 mg per kg body weight. Then the amount of pain control is recorded based on the VAS system and finally the data are analyzed. will be.

#### Category

Treatment - Drugs

## 2

### Description

Control group: The first group is given intravenous morphine sulfate at a dose of 0.1 mg per kg body weight intravenously. Then the amount of pain control will be recorded based on the VAS system and data analysis will be performed.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ayatollah Mousavi Hospital

**Full name of responsible person**

Hossein Rahmani

**Street address**

Mahdavi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956111

**Phone**

+98 24 3301 8687

**Fax**

+98 24 3301 8687

**Email**

Zums.ac.ir@Csa

**Web page address**

Http://www.zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Mahin Ganjkhani

**Street address**

No.1., Mahdavi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956111

**Phone**

+98 24 3301 8687

**Fax**

+98 24 3301 8687

**Email**

Zums.ac.ir@csa

**Web page address**

Http://www.zums.ac.ir

**Grant name****Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Hossein Rahmani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Mahdavi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956111

**Phone**

+98 24 3301 8687

**Email**

Ramdrarah@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Hossein Rahmani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Mahdavi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956111

**Phone**

+98 24 3301 6687

**Email**

Ramdrrah@gmail.com

**Postal code**

4513956111

**Phone**

+98 24 3301 8687

**Email**

Ramdrrah@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Hossein Rahmani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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**City**

Zanjan

**Province**

Zanjan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available