

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

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Zanjan

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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

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No.1., Mahdavi Blvd

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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

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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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