

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison between Intravenous Morphine and Ketofol in treatment of severe acute pain of urolithiasis resistant to ketorolac

Protocol summary

Summary

The purpose of this study is to compare the effects of morphine and Ketofol in the treatment of patients with severe urolithiasis pain that unresponsive to IV ketorolac. All patients with severe refractory to intravenous Ketorolac pain will be enrolled in this study. Patients with addiction to opioid drugs, allergy to egg and allergy to morphine will be excluded. The sample size is considered 120 patients. Patients will be divided to intervention group, treated with IV Ketofol, and the control group, treated with IV morphine. Severity of pain is measured based on the numerical pain score. At control group patient's 0.1 mg/kg intravenous morphine will be injected and then after 5 and 10 minute the Severity of pain numerically will be measured and will be documented. At intervention group patient's 0.75 mg/kg propofol plus 0.75 mg/kg ketamine intravenous will be injected and then after 5 and 10 minute the Severity of pain numerically will be measured and will be documented. Both groups will be compared in terms of pain relief.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052417812N1**

Registration date: **2014-07-17, 1393/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-17, 1393/04/26

Registrant information

Name

Gholamreza Faridaalae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 9540

Email address

faridaalae@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia Medical University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Intravenous Morphine and Ketofol in treatment of severe acute pain of urolithiasis resistant to ketorolac

Public title

comparison between morphine and ketofol in renal colic patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: all patients with severe acute pain who are resistant to IV ketorolac. exclusion criteria: allergy to morphine; allergy to egg; patients with addiction to opium; hemodynamic instability.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences; Resalat Avenue

City

Urmia

Postal code

Approval date

2014-05-20, 1393/02/30

Ethics committee reference number

umsu.rec.1393.66

Health conditions studied

1

Description of health condition studied

Urolithiasis

ICD-10 code

N 20

ICD-10 code description

Calculus of kidney

2

Description of health condition studied

Urolithiasis

ICD-10 code

N 21

ICD-10 code description

Calculus of lower urinary tract

3

Description of health condition studied

Urolithiasis

ICD-10 code

N 22

ICD-10 code description

Calculus of urinary tract in diseases classified elsewhere

4

Description of health condition studied

Urolithiasis

ICD-10 code

N 23

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Pain relief

Timepoint

Q 5 minute up to 15 minute

Method of measurement

10 numerical score with Visual Analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In control group 0.1 mg / kg / IV morphine will be injected.

Category

Treatment - Drugs

2

Description

intervention group, 0.75 mg / kg IV ketamine + 0.75 mg / kg /IV propofol will be injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Gholamreza Faridaalae

Street address

Emergency Ward, Imam Khomeini Hospital, Ershad

Avenue, Urmia
City
urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences, Resalat Avenue,Urmia

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Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urmia 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

Urmia University of Medical Sciences

Full name of responsible person

Gholamreza Faridaalae

Position

Assistant Professor

Other areas of specialty/work

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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