Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between Intravenous Morphine and Ketofol in treatment of severe acute pain of urolitiasis 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 Faridaalaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 9540

Email address

faridaalaee@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia Medical University of Medical Siences

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 urolitiasis 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 Scinces
Street address
Urmia University of Medical Scinces; ResalatAvenue
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
Urolithiasisi
ICD-10 code
N 20
ICD-10 code description
Calculus of kidney

2

Description of health condition studied
Urolithiasisi
ICD-10 code
N 21
ICD-10 code description
Calculus of lower urinary tract

3

Description of health condition studied
Urolithiasisi
ICD-10 code
N 22
ICD-10 code description
Calculus of urinary tract in diseases classified elsewhere

4

Description of health condition studied
Urolithiasisi
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 Visaul 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 Faridaalaee
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
City
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 Scineces
Full name of responsible person
Gholamreza Faridaalaee
Position
Assistant Professor
Other areas of specialty/work
Street address
Emergency Ward, Imam Khomeini hospital, Ershad Avenue, Urmia
City
Urmia
Postal code
Phone
+98 44 1345 9538
Fax
+98 44 1346 9935
Email
grf.aalae@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urmia University of Medical Scineces
Full name of responsible person
Gholamreza Faridaalaee
Position
Assistant Professor
Other areas of specialty/work
Street address
Emergency Ward, Imam Khomeini Hospital, Ershad Avenue -
City
Urmia
Postal code
Phone
+98 44 1345 9538
Fax
Email
grf.aalae@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Urmia University of Medical Scineces
Full name of responsible person
Gholamreza Faridaalaee
Position
Assistant Professor
Other areas of specialty/work
Street address
Emergency Ward, Imam Khomeini Hospital, Ershad Avenue, Urmia
City
Urmia
Postal code
Phone
+98 44 1345 9538
Fax
+98 44 1346 9935
Email
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