

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of clinical efficacy of Intravenous acetaminophen vs ketorolac to relieve pain in renal colic

Protocol summary

Summary

The aim of this single blinded randomized controlled trial (for patients) is to determine and comparison of clinical efficacy of Intravenous acetaminophen vs. ketorolac to relieve pain in renal colic. We will study a sample of patients aged 18 to 55 who presented to the emergency department of Kosar hospital in Semnan, Iran. Patients will eligible for inclusion with a history of unilateral abdominal or flank pain that the treating emergency physicians suspect to be renal colic, with ultrasonography or CT scan or intravenous pyelography (IVP) findings consistent with the diagnosis of renal colic or passage of the calculus. Only patients displaying at least a visual analog scale (VAS) $\geq 30/100$ will include. Patients cannot be include if they have a history of peptic ulcer disease, asthma, bleeding disorder (including the use of oral anticoagulant), impaired renal or hepatic function, suspected hypersensitivity to aspirin or NSAID or paracetamol, and if they are pregnant and breast-feeding women. Patients cannot be included if they have received painkillers within 6 hours before presentation and if they are younger than 18 and greater than 55 years old. We calculated that a sample size of 120 patients is necessary and they divided through randomized permuted blocks single blind into two groups. one group will receive 1 gram intravenous paracetamol and another group will receive 30 mg intravenous ketorolac. Rescue therapy is defined as the need of 5 mg intramuscular morphine if VAS at 60 minutes is more than 50% the initial VAS. The primary end point is pain relief at 60 minutes, defined as a decrease of VAS of 50% or more as compared to the initial value. The secondary end points are differences in VAS at 20, 40, 60 minutes and occurrence of side effects. A questionnaire is designed for record of demographic data and VAS points and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090223855N1**
Registration date: **2015-10-27, 1394/08/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

Name

Davood Arab

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 4042

Email address

drdavoodarab@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of clinical efficacy of Intravenous acetaminophen vs ketorolac to relieve pain in renal colic

Public title

Comparision of clinical efficacy of Intravenous acetaminophen vs ketorolac to relieve pain in renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Patients will eligible for inclusion with a history of unilateral abdominal or flank pain that the treating emergency physicians suspect to be renal colic, with ultrasonography or CT Scan or intravenous pyelography (IVP) findings consistent with the diagnosis of renal colic or passage of the calculus. Only patients displaying at least a visual analog scale (VAS) $\geq 30/100$ will include. Patients can not be include if they have a history of peptic ulcer disease, asthma, bleeding disorder (including the use of oral anticoagulant), impaired renal or hepatic function, suspected hypersensitivity to aspirin or NSAID or paracetamol, and if they are pregnant and breast-feeding women. Patients can not be include if they have received painkillers within 6 hours before presentation and if they are younger than 18 and greater than 55 years old.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

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

Ethics Ccommittee of Semnan University of Medical Sciences

Street address

Kosar Hospital, Bassije Blvd, Semnan, Iran

City

Semnan

Postal code

3519899951

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

IR.SEMUMS.REC.1394.72

Health conditions studied

1

Description of health condition studied

Acute Renal Colic

ICD-10 code

N20.9

ICD-10 code description

Urinary calculus, unspecified

Primary outcomes

1

Description

Level of pain

Timepoint

before treatment initiation and sequentially at 20,40,60 minutes

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Heart Rate

Timepoint

before treatment initiation and sequentially at 20,40,60 minutes

Method of measurement

Radial Pulse

2

Description

Blood pressure

Timepoint

before treatment initiation and sequentially at 20,40,60 minutes

Method of measurement

sphygmomanometer

3

Description

body temprature

Timepoint

before treatment initiation and sequentially at 20,40,60 minutes

Method of measurement

Thermometer(axillary)

4

Description

Respiratory rate

Timepoint

before treatment initiation and sequentially at 20,40,60 minutes

Method of measurement

Physical examination

5

Description

size of renal calculi

Timepoint

after pain relief

Method of measurement

imaging findings

6

Description

Location of renal calculi

Timepoint

after pain relief

Method of measurement

imaging findings

7

Description

paracetamol side effects

Timepoint

in all the time in care

Method of measurement

questionnaire and physical examination

8

Description

ketorolac side effects

Timepoint

in all the time in care

Method of measurement

questionnaire and physical examination

Intervention groups

1

Description

Intervention group: patients will receive 30 mg intravenous ketorolac tromethamine (brand name : ketorolac ,Caspian Tamin Pharmaceutical Company) within 15 seconds.

Category

Treatment - Drugs

2

Description

Control group: patients will receive 1 gram intravenous paracetamol (brand name : Apotel) infused in 100 ml normal saline within 15 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Kosar Medical Center

Full name of responsible person

Dr Davood Arab

Street address

KosarHospital , Bassije Blvd, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice- Chancellor for Research, Semnan University of Medical Sciences

Full name of responsible person

Dr Ali Rashidipor

Street address

Bassije Blvd. Semnan, Iran

City

Semnan

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

Yes

Title of funding source

Vice- Chancellor for Research, Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Dr Davood Arab

Position

Fellowship of Endourology

Other areas of specialty/work

Street address

Kosar Hospita, Bassije Blvd, Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7830

Fax

+98 23 3343 7837

Email

drdavoodarab@semums.ir

Web page address

<http://kosarhos.semums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Davood Arab

Position

Fellowship of Endourology

Other areas of specialty/work

Street address

Kosar hospital, Bassije Blvd, Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7830

Fax

+98 23 3343 7837

Email

drdavoodarab@semums.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Fax

+98 23 3343 7837

Email

drdavoodarab@semums.ac.ir

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