

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Efficacy of intravenous paracetamol versus intravenous morphine and intravenous ketorolac in controlling renal colic in emergency ward patients of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences

Protocol summary

Summary

Patients with flank pain diagnosed as renal colic confirmed by sonography or spiral CT scan are entered in this study. Patients are divided in 3 groups: case group (receiving intravenous apotel), control group (receiving intravenous morphine) and third group receiving 30 mg intravenous ketorolac. A questionnaire containing demographic data, diagnosis, sonographic or CT scan findings. Inclusion and exclusion criteria are recorded and severity of pain is defined by visual or verbal criteria. The nurse administers the medications randomly and 1st dose is given and after 30 minutes the pain is checked according to verbal or visual pain assessment scale; if pain is not decreased, then a dose of rescue analgesic (fentanyl) is given. The patients are observed for 6 hours in surgical emergency ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072110330N1**
Registration date: **2013-04-18, 1392/01/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-18, 1392/01/29

Registrant information

Name

Seyed Ashkan Tabibzadeh

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.atabibzadeh@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences, research department

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of intravenous paracetamol versus intravenous morphine and intravenous ketorolac in controlling renal colic in emergency ward patients of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences

Public title

Efficacy of intravenous paracetamol versus intravenous morphine and intravenous ketorolac in controlling renal colic in emergency ward patients of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: symptoms of renal colic verified by

sonography or spiral CT scan. Exclusion criteria: allergy; suspected ruptured abdominal aortic aneurysm; history of hepatic or renal insufficiency; liver or kidney transplant; history of asthma; dialysis; hemodynamic instability; suspected pregnancy; fever more than 38 celsius orally; peritoneal irritation; use of parenteral analgesic 6 hours PTA.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University of Medical Sciences Ethics Committee

Street address

Ostandari Blvd, Hormozgan University of Medical Sciences

City

Bandar-e-Abbas

Postal code

7919915519

Approval date

2013-02-27, 1391/12/09

Ethics committee reference number

H-E-C-9-1-12-1

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

N20-23

ICD-10 code description

Calculus of urinary tract

Primary outcomes

1

Description

Pain

Timepoint

Before pain onset or 15-30 mins after onset

Method of measurement

Verbal and visual

2

Description

Pain relief

Timepoint

30 minutes after intervention

Method of measurement

Verbal or visual pain assessment scale

Secondary outcomes

empty

Intervention groups

1

Description

Group 3: morphin sulfate 10mg IV infusion in 100cc normal saline 0.9%

Category

Treatment - Drugs

2

Description

Group 1: paracetamol iv infusion in 100cc normal saline 0.9% over 15 minute

Category

Treatment - Drugs

3

Description

Group 2: ketorolac 30 mg IV infusion in 100cc normal saline 0.9% over 15 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department, Shahid Mohamadi hospital

Full name of responsible person

Dr Ashkan Tabibzadeh

Street address

Jomhouri boulevard, Shahid Mohamadi hospital

City

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atabibzade@hums.ac.ir; ashkantz@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Resarch department, hormozgan university of medical sciences

Full name of responsible person

Dr Abdolazim Nejatizadeh

Street address

Jomhouri Boulevard, Shahid Mohamadi hospital, Research department

City

Bandar abbas

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

Yes

Title of funding source

Resarch department, hormozgan 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**

Hormozgan University of Medical Sciences

Full name of responsible person

Dr Seyed Ashkan Tabibzadeh

Position

Emergency medicine specialist- Head of Emergency ward- Head of Trauma and Eemergency Research Center

Other areas of specialty/work**Street address**

Shahid Mohammadi hospital- Emergency ward

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Fax**Email****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Hormozgan University of Medical Sciences

Full name of responsible person

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Position

Emergency Medicine Specialist/ Head of Emergency Department/ Head of Trauma and Emergency Resaerch C

Other areas of specialty/work**Street address**

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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