

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

A comparative study on the effect of Ketorolac and Hyosine on patients pain controlled with renal colic complications, a randomized control trial

Protocol summary

Study aim

A comparative study on the effect of Ketorolac and Hyosine on patients pain controlled with renal colic complications

Design

This is a parallel randomized clinical trial that will perform on 186 patients with renal colic. Randomization will perform with permuted blocked randomization using SPSS syntax. The block size will be 4. This study will enroll for 4 months.

Settings and conduct

This study will conduct as a clinical trial study with 186 patients who will refer to Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study. In this study; clinical caregiver and the analyzer will blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 16 and 75 years of patients; stable vital signs, definitive diagnosis of renal colic (with or without urinary tract stones in sonography); no underlying urinary tract disorders; no use of analgesic in 24 hours before referral and satisfaction with research participation. Exclusion criteria: history of allergy to ketorolac and hyosine; unstable hemodynamics of patients; evidence of acute abdominal problems (tenderness, guarding, rebound and rebound tenderness); pregnancy, Breastfeeding; known renal failure; known liver failure; a history of active gastric or peptic ulcer disease or gastrointestinal bleeding; addiction to a variety of opium and dissatisfaction with the plan.

Intervention groups

Patients entered into the study are divided into intervention and control groups. In the intervention group, treatment with ketorolac ampule will be prescribed. In the control group, treatment with hyocine ampule will be prescribed.

Main outcome variables

Reducing the severity of kidney pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N19**

Registration date: **2020-07-01, 1399/04/11**

Registration timing: **prospective**

Last update: **2020-07-01, 1399/04/11**

Update count: **0**

Registration date

2020-07-01, 1399/04/11

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

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+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-21, 1399/04/31

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of Ketorolac and Hyosine on patients pain controlled with renal colic complications, a randomized control trial

Public title

Comparison of the effect of ketorolac and hyosine on pain control in patients with renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 16 and 75 years of patients; Stable vital signs; Definitive diagnosis of renal colic (with or without urinary tract stones in sonography); Absence of underlying urinary tract disorders; Do not use any analgesic for 24 hours before visiting; Satisfaction of research participation.

Exclusion criteria:

Unstable hemodynamics of patients; History of allergy to ketorolac and hyosine; Evidence of Acute Abdominal Problems (tenderness, guarding, rebound, and rebound tenderness); Pregnancy; Breastfeeding; Renal failure is known; Liver failure is known; A history of active gastric ulcer disease or gastrointestinal bleeding; Addiction to a variety of opium; Dissatisfaction with participating in the project.

Age

From **16 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **186**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using permuted block randomization method using blocked random allocation syntax in SPSS software. For calculation sample size, number of blocks and block size was determined. Block size was 4. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

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Shahroud

Province

Semnan

Postal code

3616647555

Approval date

2018-10-12, 1397/07/20

Ethics committee reference number

IR.SHMU.REC.1397.141

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

MF56

ICD-10 code description

A severe paroxysmal pain in the flank radiating to the groin, scrotum or labia, caused by blockage of the renal pelvis or ureter most commonly by a renal stone. May be associated with nausea and vomiting.

Primary outcomes

1

Description

Reduce the severity of renal pain

Timepoint

Once every hour

Method of measurement

Ask the patient and use the visual analog score (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for patients in this group, after administration of serum, 30 mg of ketorolac (one ampule) is given intramuscular, and if pain is not controlled within 2 hours, the same dose will be repeated.

Category

Treatment - Drugs

2

Description

Control group: For patients in this group after administration of serum, 20 mg of hyosine (one ampule) is administered intramuscular and if the pain is not controlled within 2 hours, the same dose will be repeated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahroud

Full name of responsible person

Dr. Hossain Amiri Lorghani

Street address

Imam Hossein Hospital., End Imam street., Shahroud , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

Street address

Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research; Shahroud University medical and 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

Shahroud University of Medical Sciences

Full name of responsible person

Sara kianmehr

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Imam Hossein Hospital, End Imam street, Shahroud,

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available