

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of adding oral clonidine to standard treatments on pain intensity of patients with acute renal colic

Protocol summary

Study aim

Efficacy of adding oral Clonidine to standard treatment in acute renal colic

Design

Four arm triple blinded, parallel group, randomized clinical trial

Settings and conduct

Scientist prepare and label the drugs and placebo. Patients with acute renal colic who admitted in Alzahra and Kashani hospital (Isfahan city) divided in 4 group after randomization and study manager start treating patient due to randomized numeric table; blinded to treatment protocol. Patients in different groups receive below treatments: group 1: 10 minutes infusion of 0.1 mg/kg Morphine diluted in 100 ml normal saline and 1 pill of oral Placebo group 2: 10 minutes infusion of 30mg Ketorolac diluted in 100 ml normal saline and 1 pill of oral Placebo group 3: 10 minutes infusion of 0.1 mg/kg Morphine diluted in 100 ml normal saline and 1 pill of 0.2 mg oral Clonidine group 4: 10 minutes infusion of 30mg Ketorolac diluted in 100 ml normal saline and 1 pill of 0.2 mg oral Clonidine Study observer check and record complications and pain severity with VAS score in beginning of study and after 20 minutes and 40 minutes of treatment; blinded to treatment protocol. Study manager and scientist inject 0.05 mg/kg IV Morphine if patient pain doesn't reduce after 40 minutes of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-55 years old; normal blood pressure
Exclusion criteria: uncontrolled pain; drug complications

Intervention groups

Patients are divided in 4 group after randomization: group 1) receive IV Morphine and Placebo group 2) receive IV ketorolac and Placebo group 3) receive IV Morphine and oral Clonidine group 4) receive IV Ketorolac and oral Clonidine

Main outcome variables

Clonidine efficiency in patient pain control and patient

need to multiple dose of analgesic agents

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130108012072N11**

Registration date: **2020-10-22, 1399/08/01**

Registration timing: **retrospective**

Last update: **2020-10-22, 1399/08/01**

Update count: **0**

Registration date

2020-10-22, 1399/08/01

Registrant information

Name

Mehrdad Esmailian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 3482

Email address

m_esmailian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-05-21, 1399/03/01

Trial completion date

2020-05-21, 1399/03/01

Scientific title

Effect of adding oral clonidine to standard treatments on pain intensity of patients with acute renal colic

Public title

Clonidine efficacy in acute renal colic

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Agreement for entering to the study No Mental Retardation Non pregnant No breast feeding Didn't use of analgesic agents since 4 hours ago No sensitivity to Morphine or Ketorolac or Clonidine Blood Pressure $\geq 110/70$ mm Hg No history of chronic liver or kidney injury VAS (Visual Analog Score) >4

Exclusion criteria:

Analgesic agents use since 4 hours ago History of drug reaction

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group. The researcher begins to read the numbers in a predetermined manner and the patients are divided.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drugs are prepared with scientist and labeled (scientist is blinded to patient's treatment group and efficacy or complications of each group). Patients are selected with randomized numeric table and don't aware about treatment protocol. Manager use treatment pathway base on patient randomization; blinded about drug that be used and record result and complications.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Alzahra general hospital, Sofeh blv., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8175898595

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.MUI.MED.REC.1397.340

Health conditions studied**1****Description of health condition studied**

Acute renal colic

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

Primary outcomes**1****Description**

Pain severity score with Visual Analog Scale

Timepoint

Study beginning, 20 minutes and 40 minutes after treatment

Method of measurement

Visual Analog Scale

2**Description**

Drug complications

Timepoint

Study beginning, 20 minutes and 40 minutes after treatment

Method of measurement

Standard questionnaire form

Secondary outcomes

1

Description

Insufficient pain control

Timepoint

40 minutes after treatment

Method of measurement

Visual Analog Scale

Intervention groups

1

Description

Intervention group 1: 0.1 mg/kg Morphine diluted in 100 ml normal saline in 10 minutes infusion and 1 pill of 0.2 mg oral Clonidine

Category

Treatment - Drugs

2

Description

Intervention group 2: 30 mg Ketorolac diluted in 100 ml normal saline in 10 minutes infusion and 1 pill of 0.2 mg oral Clonidine

Category

Treatment - Drugs

3

Description

Control group 1: 0.1 mg/kg Morphine diluted in 100 ml normal saline in 10 minutes infusion and 1 pill of oral Placebo

Category

Treatment - Drugs

4

Description

Control group 2: 30 mg Ketorolac diluted in 100 ml normal saline in 10 minutes infusion and 1 pill of oral Placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra general hospital

Full name of responsible person

Mehrdad Esmailian

Street address

Alzahra general hospital, sofeh Blv.

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Isfahan

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Phone

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m_esmailian@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mehrdad Esmailian

Street address

Kashani hospital, Kashani street

City

Isfahan

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m_esmailian@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezarjerib Ave., Azadi square, Isfahan, Iran

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sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehrdad Esmailian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Whole of data after coding

When the data will become available and for how long

Accessibility after 2021

To whom data/document is available

Everyone

Under which criteria data/document could be used

For seemingly studies data released to academic chairman's

From where data/document is obtainable

Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Emailing to m_esmailian@med.mui.ac.ir

Comments