

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of intravenous lidocaine analgesic effect versus fentanyl in acute renal colic pain control

Protocol summary

Summary

Objective: Comparison of analgesic effect of intravenous Lidocaine versus Fentanyl **Design:** During a prospective double blinded study, the patient of 18-65 years old with pain of renal colic nature referred to Emergency Department were included in the trial. For the women of fertility age pregnancy test applied to rule out pregnancy. The Sample size was 40 patients, which randomized in a double blind study in one hospital center. **Setting and Conduct:** Electrocardiogram has been arranged and interpreted for patients to confirm there is no concurrent dysrhythmia or ischemic heart disease. Then the patients have been randomized in a double blind study of 2 groups. For first group intravenous bolus dose of lidocaine of 1.5 mg/kg during 2 minutes were administered and the second group intravenous fentanyl with bolous dose of 1.5 microgram/kg under cardiac monitoring with responsibility of an Emergency Medicine specialist. Patients symptoms such as vital signs, nausea, vomiting were evaluated and pain score of arrival, 5, 10, 15 and 30 were recorded based on visual analog scale. Patient consent form was signed and the course of the study was described for all patients. The patients whom have pain after 30 minutes of trial will receive 0.1 mg/kg as an adjunctive pain killer. Renal pain diagnosis in both groups will confirm with sonography or spiral CT scan and hematuria in urine analysis. The patients with unconfirmed diagnosis will omit from the study. All questionnaire data will collect by one operator who is not aware of the prescribed drug to avoid any bias. The results will statistically analyze and drug analgesic effect will evaluate with Mann Whietney test using SPSS software. Participant including major eligibility criteria: Renal colic patients between 18-65 years old which had no history of ischemic heart disease and dysrhythmia and hepatic and renal disease and no history of Monoamine oxidase inhibitor and no sensitivity to lidocaine and opioids. **Intervention:** For first group intravenous bolus dose of lidocaine of 1.5 mg/kg during 2

minutes were administered and the second group intravenous fentanyl with bolous dose of 1.5 microgram/kg under cardiac monitoring with responsibility of an Emergency Medicine specialist. Patients symptoms such as vital signs, nausea, vomiting were evaluated and pain score of arrival, 5, 10, 15 and 30 were recorded based on visual analog scale. main outcome measures : Pain Score

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081415446N12**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Hassan Motamed

Name of organization / entity

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University of Medical Sciences , Ahvaz , Iran

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Expected recruitment start date

2018-01-01, 1396/10/11

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of intravenous lidocaine analgesic effect versus fentanyl in acute renal colic pain control

Public title

Evaluation of intravenous lidocaine versus fentanyl as a pain killer in acute renal colic pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Study Inclusion Criteria: Acute Pain of Renal Colic of age 18-65 years old Study Exclusion Criteria: Monoamine oxidase inhibitor Consumption within last 2 weeks, Cardiac, Hepatic or renal disease, dysrhythmia, sensitivity to lidocaine or fentanyl, pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Block Randomization

Secondary Ids

empty

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan St, Ahvaz, Iran

City

Ahvaz

Postal code**Approval date**

2013-12-23, 1392/10/02

Ethics committee reference number

ajums.REC.1392.324

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

Acute Pain Control in acute renal colic

ICD-10 code

N20.0

ICD-10 code description

Renal calculus or stone

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

Numeric Variable of severity of pain

Timepoint

0,5,10,15,30 minutes

Method of measurement

VAS Scoring

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention: 1.5 mg /kg intravenous lidocaine within 2 minutes slow infusion under cardiac monitoring

Category

Treatment - Drugs

2**Description**

Control: 1.5 microgram/kg Fentanyl stat

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hassan Motamed

Street address

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City

Ahvaz

2**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person**Street address****City**

Ahvaz

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Hassan Motamed

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Golestan St ,Ahvaz Jundishapur University of Medical
Sciences, Ahvaz, Iran

City

Ahvaz

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, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz, Iran

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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Assistan Professor of Emergency Medicine

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Hassan Motamed

Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**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