Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary

Objective: Comparison of analgesic effect of interavenous 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

Emegency Department , Ahvaz Jundishapour University of Medical Sciences , Ahvaz , Iran

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

motamed-h@ajums.ac.ir

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, disrhythmia, 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
Ethic Commitee 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
Nummeric 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 interavenous 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
Ahvaz
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 sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Hassan Motamed
Street address
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
Hassan Motamed
Position
Assistan Professor of Emergency Medicine
Other areas of specialty/work
Street address
Golestan St,Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
City
Ahvaz
Postal code
Phone
+98 61 3374 3099
Fax
Email
hasan_motamed@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Hassan Motamed
Position
Assistant Professor of Emergency Medicine
Other areas of specialty/work
Street address
Golestan St,Ahvaz Jundishapur University of Medical Sciences, Ahvaz ,Iran
City
Ahvaz
Postal code
Phone
+98 61 3374 3099
Fax
Email
hasan_motamed@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Hassan Motamed
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
00
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