Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compare the efficacy of intravenous ketorolac and fentanyl transdermal patch for pain relief in patients with inflammation of the gallbladder colic attacks

Protocol summary

Summary

Objectives, Compare the differences in clinical testing pain NRS (along with control respiratory rate, heart rate, paradoxical pulse, body temperature, GCS, talking evaluated) before and after the intervention listed from time to time. (2) Design, Clinical trials (3) Setting and conduct, This study was performed double blind. 260 patients referred to Imam Khomeini and Golestan hospitals with biliary colic to be enrolled. First patients to be seen and physical examination are assessed. They will be recorded in the record patients' vital signs and also before any clinical trial resuscitation equipment will be ready. (4) Participants including major eligibility criteria, Inclusion criteria: 1 - MINIMUM AGE 18 and maximum65 years; 2 -Having pain paunch of evaluation by the physician or assistant emergency medicine as biliary colic diagnose; 3 - Unprecedented of stone of the bladder by National rivalries diagnose. exclusion criteria: 1 - Aaged under 18 and Bali 65 years; 2 - The temperature above 38 ºc; 3 - Allergic to ketorolac and other nsaid; 4 -Sensitivity to transdermal fentanyl gasteroentrology; 5 - Patients that tired King outside; 6 - Treatment of anti-making blood in 4 recent weeks; 7 - History ulcers active during 6 recent months; 8 - The history of the disease of blood planning provider; 9 - Patients with safety system, disease of the hepatitis; 10 - Disease of the renal arteries; 11 - Medical problem, acute heart patients; 12 - Pregnant women; 13 - A history of peptic ulcer and pancratit; 14 - Addicts to drugs, mopper foods or any inhalants something; 15 - Failure to confirm biliary colic diagnosed with sonography; 16 -Any problems normal or abnormal in your skin that may attract medicine the skin affected the "having a lot of hair or skin disease; 17 - Receive any kind of pain medication or mopper foods in 8 hours before entering the emergency room (5) Intervention, Injectable ketorolac for intravenous administration of fentanyl skin patch to measure and evaluate pain in patients (6) main outcome measures (variables), Age, gender, temperature, respiratory rate, pulse, blood pressure, pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112725261N1**
Registration date: **2016-02-28, 1394/12/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-28, 1394/12/09

Registrant information

Name

Farhad Zarei Ghanavati

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Jundishapur University of Medical Sciences, Golestan Hwy, Ahvaz, Khozestan, Iran

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the efficacy of intravenous ketorolac and fentanyl transdermal patch for pain relief in patients with inflammation of the gallbladder colic attacks

Public title

Evaluation of IV Ketorolac with Fentanyl Transdermal Patch effectiveness in relieving pain in biliary colic attacks

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1 - MINIMUM AGE 18 and maximum65 years; 2 -Having pain paunch of evaluation by the physician or assistant emergency medicine as biliary colic diagnose; 3 - Unprecedented of stone of the bladder by National rivalries diagnose; exclusion criteria: 1 - Aged under 18 and Bali 65 years; 2 - The temperature above 38 ºc; 3 - Allergic to ketorolac and other nsaid; 4 - Sensitivity to transdermal fentanyl gasteroentrology; 5 - Patients that tired King outside; 6 - Treatment of anti-making blood in 4 recent weeks; 7 - History ulcers active during 6 recent months; 8 - The history of the disease of blood planning provider; 9 - Patients with safety system, disease of the hepatitis; 10 - Disease of the renal arteries; 11 - Medical problem, acute heart patients; 12 - Ppregnant women; 13 - A history of peptic ulcer and pancratit; 14 - Addicts to drugs, mopper foods or any inhalants something; 15 - failure to confirm biliary colic diagnosed with sonography; 16 -Any problems normal or abnormal in your skin that may attract medicine the skin affected the "having a lot of hair or skin disease; 17 - Receive any kind of pain medication or mopper foods in 8 hours before entering the emergency room

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **260**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

...

Secondary trial Id

...

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Jondi Shapour University of Medical Sciences Ethics Committee

Street address

Jondi Shapour University Ethics Committee, Jondi Shapour University, Golestan Hwy, Ahwaz, Khozestan, Iran

City

Ahwaz

Postal code

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.AJUMS.REC.1394.405

Health conditions studied

1

Description of health condition studied

biliary colic

ICD-10 code

K80.5

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes

1

Description

pain

Timepoint

0 and 30 and 60 min and 3-4 h after intervetion

Method of measurement

Numeric Rating Scale metod

Secondary outcomes

1

Description

Side effects of Ketorolac and Fentanyl

Timepoint
0 and 30 and 60 min and 3-4 h after intervetion
Method of measurement
Vital sign,s

Intervention groups

1

Description
Ketorolac IV 30 mg and Transdermal pach with out drugs (Placebo) to a group of patients given only once .
Category
Treatment - Drugs

2

Description
Transdermal Fentanyl 75 mic/gr and plaebo ampuls for the second group of patients who are prescribed only once
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini and Golestan Hospital
Full name of responsible person
Farhad Zarei Ghanavati
Street address
Emergency department, Emam Khomeini hospital, Emam Khomeini St, Ahwaz, Khozestan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Nader Saki, Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences
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Ahvaz Jundishapur University, Golestan Hwy, Ahwaz, Khozestan, Iran
City
Ahwaz
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
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
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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