

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 maximum 65 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 over 65 years; 2 - The temperature above 38 °C; 3 - Allergic to ketorolac and other NSAID; 4 - Sensitivity to transdermal fentanyl gastroenterology; 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 pancreatitis; 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 maximum 65 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 °C; 3 - Allergic to ketorolac and other nsaid; 4 - Sensitivity to transdermal fentanyl gastroenterology; 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 pancreatitis; 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 intervention

Method of measurement

Numeric Rating Scale method

Secondary outcomes

1

Description

Side effects of Ketorolac and Fentanyl

Timepoint

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

Method of measurement

Vital sign,s

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

Ketorolac IV 30 mg and Transdermal patch with out drugs (Placebo) to a group of patients given only once .

Category

Treatment - Drugs

2**Description**

Transdermal Fentanyl 75 mic/gr and placebo 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

City

Ahwaz

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

Street address

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****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Farhad Zarei Ghanavati

Position

Assitant of emergency medicine

Other areas of specialty/work**Street address**

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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

Emergency medicine specialist

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Person responsible for updating data

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Full name of responsible person

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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