Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of analgesic effect of haloperidol plus morphin with morphin alone in patients with acute renal colic presenting to emergency department

Protocol summary

Summary

objectives: to comparison of analgesic effect of haloperidol plus morphine sulfate in contrast to morphine sulfate alone in renal colic design setting and conduct: in this clinical trial that is a phase 2 and 3 study and done on two groups case and control with 70 patients in each one, we give morphine and haloperidol to case group and morphine alone to control group and then comparise these two with each other at minute 60, at last each patient with pain score 5 or upper will get intravenous fentanyl inclusion criteria: clinical and para-clinical findings suggestive of renal colic in 18-55 years old patients exclusion criteria: decreased level of consciousness; pregnancy; heart disease; renal disease; allergy to morphine or haloperidol; severe side effects like nausea and vomiting main outcome measures: patient's pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092224136N1**
Registration date: **2015-11-22, 1394/09/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-22, 1394/09/01

Registrant information

Name

Ali Delirrooyfard

Name of organization / entity

Ahvaz,Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice challencor for reasearch of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-08-02, 1394/05/11

Expected recruitment end date

2016-02-02, 1394/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of analgesic effect of haloperidol plus morphin with morphin alone in patients with acute renal colic presenting to emergency department

Public title

The comparison of analgesic effect of haloperidol plus morphin with morphin alone in patients with acute renal colic presenting to emergency department

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: clinical and para-clinical evidence of renal colic in 18-55 years old patients with flank pain exclusion criteria: decreased level of consciousness; age below 18 or above 55 years old; renal disease; heart disease; pregnancy; allergy to haloperidol or morphine;

severe side effects like nausea and vomiting

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Method of closed envelopes that randomely puts the patient in one of intervention or control groups will be used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Research Assistant, Next to central Building, Ahvaz Jundishapur University of Medical Sciences, University town, Ahvaz

City

Ahvaz

Postal code

Approval date

2015-04-29, 1394/02/09

Ethics committee reference number

IR.AJUMS.REC.1394.173

Health conditions studied

1

Description of health condition studied

Urilothiasis

ICD-10 code

N23

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Visual analoge scale for pain

Timepoint

Before intervention, 20 minutes after intervention, 40 minutes after intervention, 60 minutes after intervention

Method of measurement

millimeter

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

Before Intervention, 20 Minutes after intervention, 40 minutes after intervention, 60 minutes after intervention

Method of measurement

Questionnaire

2

Description

Extrapyramidal side effects

Timepoint

Before Intervention, 20 Minutes after intervention, 40 minutes after intervention, 60 minutes after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Group: Morphine Sulfate intravenously 0.1 mg per kilogram (Dr. Abidi manufacturer) Haloperidol 5mg intramuscular (Iran Pharma manufacturer) Fentanyl 1mcg per kilogram intravenously (Iran Pharma manufacturer)

Category

Treatment - Drugs

2

Description

Control group: Morphine sulfate 0.1mg per kilogram intravenously (Dr. Abidi manufacturer) Fentanyl 1mcg per kilogram intravenously (Iran Pharma manufacturer)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz
Full name of responsible person
Dr. Ali Delirrooyfard
Street address
Imam Khomeini Hospital, 24metri Street, Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice challencor for reasearch of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Nader Saki
Street address
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice challencor for reasearch of 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
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Person responsible for updating data

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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*