Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 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
Country
Iran (Islamic Republic of)
Phone
+98 612229155
Email address
delirrooyfard-a@ajums.ac.ir

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Ali Delirrooyfard

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

3rd Phase, 17th Street, Kianpars

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

Adelir1982@gmil.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Ali Delirrooyfard

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

3rd Phase, 17th Street, Kianpars

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

Adelir1982@gmil.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Ali Delirrooyfard

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

3rd Phase, 17th Street, Kianpars

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

Adelir1982@gmil.com

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*