Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of intravenous Acetaminophen and Morphine sulfate for abdominal pain management in patients with acute abdomen

Protocol summary

Summary

The objective of this randomized, double-blind clinical trial is to compare the morphine sulfate and intravenous acetaminophen in pain management of patients with surgical acute abdomen who were admitted to emergency department of Fatemi Hospital of Ardabil. 120 patients with acute abdomen will be assigned into the study randomly. Inclusion criteria of the study are Patients above 18 years; stable vital signs; acute abdominal pain; colicky pain in nature. Exclusion criteria of the study are Patients with a history of hypersensitivity to morphine or other opioids; proven or probable pregnancy; breastfeeding; any drug addiction and get an analgesic drugs since six hours before referring to the emergency department. Demographic data, pain severity in admission to the emergency department and 30 minutes after injection, vital signs in admission, side effects, and clinical findings will recorded questionnaires. The pain level, tenderness and the rebound tenderness of the patients will determined by the Visual Analog scale. The subjects will be divided into two groups A and B randomly. The intravenous acetaminophen (15 mg/kg/100cc normal saline in the form of intravenous infusion for 30 minutes) will be administered for group (A) and intravenous morphine sulfate (0.1 mg/kg Slow-acting intravenous injection for 1.5 to 2 minutes) will be administered for group (B). After 30 minutes, the patient's pain is re-examined. Changes in the patient's pain, tenderness, rebound tenderness and side effects will documented in two groups and they will compared. Finally, the collected data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017110427097N5**

Registration date: **2017-11-17, 1396/08/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-17, 1396/08/26

Registrant information

Name

Dr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous Acetaminophen and Morphine sulfate for abdominal pain management in patients with acute abdomen

Public title

Effect of intravenous Acetaminophen for abdominal pain management in patients with acute abdomen

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients above 18 years; stable vital signs; acute abdominal pain. Exclusion criteria: Patients with a history of hypersensitivity to morphine or other opioids; proven or probable pregnancy; breastfeeding; drug addiction; get an analgesic drugs since six hours before admission to the emergency department.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardebil University of Medical Sciences

Street address
Ardebil University of Medical Sciences, daneshghah ave, Ardebil, Iran

City
Ardebil

Postal code

Approval date
2017-08-27, 1396/06/05

Ethics committee reference number
IR.ARUMS.REC.1396.87

Health conditions studied

1

Description of health condition studied
Acute abdomen

ICD-10 code
R10.0

ICD-10 code description
Acute abdomen

Primary outcomes

1

Description
Pain control

Timepoint
Before the intervention, 30 minuts after the intervention

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Side Effects

Timepoint
Before the intervention, 30 minuts after the intervention

Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group (1): Acetaminophen, 15 mg/kg/100cc normal saline, intravenous infusion, for 30 minutes

Category
Treatment - Drugs

2

Description
Intervention group (2): morphine sulfate, 0.1 mg/kg, intravenous injection, for 1.5 to 2 minutes

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemi Hospital

Full name of responsible person
Mohammad Mosanen Tabatabaii

Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran

City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Ardebil University of Medical Sciences
Full name of responsible person
Dr Shahram Habibzadeh
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
City
Ardebil
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 of Ardebil 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
Ardebil University of Medical Sciences
Full name of responsible person
Mohammad Mosanen Tabatabaii
Position
Medical student
Other areas of specialty/work
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
City
Ardebil
Postal code
Phone
+45 33 51 20 06
Fax
Email
Tabatabaii_MM70@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardebil University of Medical Sciences
Full name of responsible person
Dr Jafar Ghobadi
Position
Surgeon
Other areas of specialty/work
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
City
Ardebil
Postal code
Phone
+98 45 3351 2006
Fax
Email
J.ghobadi@arums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ardebil University of Medical Sciences
Full name of responsible person
Mohammad Mosanen Tabatabaii
Position
Medical student
Other areas of specialty/work
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
City
Ardebil
Postal code
Phone
+98 45 3351 2006
Fax
Email
Tabatabaii_MM70@yahoo.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