

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Registration timing: **prospective**

#### 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.

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

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017110427097N5**

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

#### 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 minutes after the intervention

#### **Method of measurement**

Visual Analog Scale

## **Secondary outcomes**

### 1

#### **Description**

Side Effects

#### **Timepoint**

Before the intervention, 30 minutes 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 Tabatabaai

##### **Street address**

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

##### **City**

Ardebil

## 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 Tabatabaai

**Position**

Medical student

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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Dr Jafar Ghobadi

**Position**

Surgeon

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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*