# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jun 2026

## Randomized clinical trial comparing intravenous Acetaminophen with Morphine on pain and peritoneal irritation signs in patients with acute surgical abdomen

## Protocol summary


**Summary**

(1) Objectives: Our aim in this study is to compare intravenous Acetaminophen with morphine on pain and peritoneal irritation signs in patients with acute surgical abdomen. (2) Design: In a double blinded study, one hundred and twenty patients from both genders referring to emergency department, Imam Reza Hospital, Tabriz with abdominal pain will be studied. Patients are diagnosed with acute surgical abdomen and are going to be transported to operation room. They will be included in the clinical trial after qualifying the inclusion and exclusion criteria and obtaining the informed consent. (3) Setting and conduct: One hundred and twenty patients will be randomized into two groups of 60. Participants will be chosen from patients with acute surgical abdomen. Inclusion criteria are patients diagnosed with acute surgical abdomen; age between 12 and 70 years old. Exclusion criteria are patients with a history of drug addiction; patients with a history of narcotic or sedative injection in the last week. (4) Intervention: Just before surgery morphine will be administered for one groups with a 0.1 mg/kg and for the other group intravenous acetaminophen will be administered with a dose of 15 mg/kg. (5) Main outcome measures: Patient's pain, tenderness and rebound tenderness will be evaluated based on visual analog scale before injection. Thirty minutes after the injection, patient's pain will be examined and evaluated again.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013052311067N2**
Registration date: **2013-07-20, 1392/04/29**
Registration timing: **retrospective**
Last update:
Update count: **0**

**Registration date**

2013-07-20, 1392/04/29

**Registrant information**


**Name**
Mahboub Pouraghaei
**Name of organization / entity**
Tabriz University of Medical Science
**Country**
Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice chancellor for research, Tabriz University of Medical Sciences


**Expected recruitment start date**

2013-03-21, 1392/01/01

**Expected recruitment end date**

2013-06-22, 1392/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Randomized clinical trial comparing intravenous Acetaminophen with Morphine on pain and peritoneal irritation signs in patients with acute surgical abdomen

**Public title**

Comparison of injection form of acetaminophen with morphine

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion criteria: Patients diagnosed with acute surgical abdomen; age between 12 and 70 years old. Exclusion criteria: Patients with a history of drug addiction; patients with a history of narcotic or sedative injection in the last week.

**Age**
From **12 years** old to **70 years** old

**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**
For randomizing patients into two groups, we used pocket method. Numbers from 1 to 120 were put in some pockets which were similar in size and color and were shuffled. While including a patient in the study one pocket was chosen randomly. If the figure was in range of 1 to 60, patient was placed in acetaminophen group and if it was in range of 61 to 120 patient was placed in morphine group. We used a double blinded study to prevent research outcomes from being influenced by the placebo effect or observer bias. In this study, neither the emergency physician nor the patient knew about the administered drug (morphine or acetaminophen)

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Tabriz University of Medical Sciences

**Street address**
Ethics committee، Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

**City**
Tabriz

**Postal code**

**Approval date**
2012-03-26, 1391/01/07

**Ethics committee reference number**
91170

## Health conditions studied

### 1

**Description of health condition studied**
Abdominal pain and tenderness

**ICD-10 code**
R10.0

**ICD-10 code description**
Severe abdominal pain (generalized)(localized)(with abdominal rigidity)

## Primary outcomes

### 1

**Description**
Patient's pain

**Timepoint**
Before injection, 30 minutes after injection

**Method of measurement**
Visual analogue scale

### 2

**Description**
Patient's abdominal tenderness

**Timepoint**
Before injection, 30 minutes after injection

**Method of measurement**
Physical exam and clinical evaluation

### 3

**Description**
Patient's abdominal rebound tenderness

**Timepoint**
Before injection, 30 minutes after injection

**Method of measurement**
Physical exam and clinical evaluation

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
In acetaminophen group, one shot of intravenous acetaminophen (trade name: Apotel) will be injected with a dose of 15 mg/kg intravenously.

**Category**
Treatment - Drugs

**2**

**Description**
In morphine group, one shot of morphine (trade name: MS) will be injected with a dose of 0.1 mg/kg intravenously.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Reza Hospital
**Full name of responsible person**
Peyman Emamverdizadeh
**Street address**
Department of Emergency Medicine, Imam Reza Hospital, Daneshgah Square, Tabriz
**City**
Tabriz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. Seyyed Kazem Shakouri
**Street address**
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square, Tabriz
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Tabriz
**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, Tabriz 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**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Department of Emergency Medicine, Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. Mahboub Pouraghaei
**Position**
Assistant Professor/ Specialist in Emergency Medicine
**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
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Emergency Medicine resident
**Full name of responsible person**
Dr. Peyman Emamverdizadeh
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Tabriz University of Medical Sciences
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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*

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|---|---|
| **Data Dictionary** | *empty* |