

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

City

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

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Emergency Medicine resident

Full name of responsible person

Dr. Peyman Emamverdizadeh

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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

