

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Acetaminophen, Pethidine and Ibuprofen on pain relief in patients with acute cholecystitis: a triple blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of Acetaminophen, Pethidine and Ibuprofen on pain relief in patients with acute cholecystitis.

Design

A triple blind randomized clinical trial.

Settings and conduct

The eligible patients with acute cholecystitis who will refer to Besat Hospital during the study period will be enrolled into the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 75 years; acute cholecystitis. Exclusion criteria: Pregnancy; using analgesic within pass 6 hours; addiction to narcotic or psychedelic; contraindication of Acetaminophen, Pethidine, or Ibuprofen; chronic renal failure.

Intervention groups

Intervention group 1: Intravenous infusion of 10 mg/kg Acetaminophen in 100 ml normal saline within 30 minutes single dose. Intervention group 2: Intravenous infusion of 10 mg/kg Ibuprofen in 100 ml normal saline within 30 minutes single dose. Intervention group 3: Intravenous infusion of 1 mg/kg Pethidine in 100 ml normal saline within 30 minutes single dose.

Main outcome variables

Primary outcome: Measuring the severity of pain
Secondary outcome: Assessing nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201710059014N191**
Registration date: **2017-10-05, 1396/07/13**
Registration timing: **prospective**

Last update: **2019-03-07, 1397/12/16**

Update count: **1**

Registration date

2017-10-05, 1396/07/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Acetaminophen, Pethidine and Ibuprofen on pain relief in patients with acute cholecystitis: a triple blind randomized clinical trial

Public title

Comparison of the effect of Acetaminophen, Pethidine and Ibuprofen on pain relief in patients with acute cholecystitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 75 years; Acute cholecystitis

Exclusion criteria:

Pregnancy; using analgesic within pass 6 hours; Addiction to narcotic or psychedelic; Contraindication of Acetaminophen, Pethidine, or Ibuprofen; Chronic renal failure

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The shape of the medications will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The

analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

9183511324

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.UMSHA.REC.1396.409

Health conditions studied**1****Description of health condition studied**

Acute cholecystitis

ICD-10 code

K81.0

ICD-10 code description

Acute cholecystitis

Primary outcomes**1****Description**

Measuring severity of pain

Timepoint

before infusion and 30, 60, and 90 minutes after infusion

Method of measurement

using Visual Analog Scale (VAS)

Secondary outcomes**1****Description**

Assessing nausea and vomiting

Timepoint

before infusion and 30, 60, and 90 minutes after infusion

Method of measurement

by taking history

Intervention groups

1

Description

Intervention group 1: Intravenous infusion of 10 mg/kg Acetaminophen in 100 ml normal saline within 30 minutes single dose.

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous infusion of 10 mg/kg Ibuprofen in 100 ml normal saline within 30 minutes single dose.

Category

Treatment - Drugs

3

Description

Intervention group 3: Intravenous infusion of 1 mg/kg Pethidine in 100 ml normal saline within 30 minutes single dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mohammad Jafari Azandaryani

Street address

Besat Hospital, Shahed Square

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sharifi333@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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 and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Besat Hospital

Full name of responsible person

Dr Rasool Salimi

Position

Specialist of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Name of organization / entity

Besat Hospital

Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Latest degree

Ph.D.