Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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

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Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
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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
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Person responsible for updating data

Contact

Name of organization / entity
Department of Epidemiology

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Associate Professor

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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