Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of intravenous ibuprofen, intravenous acetaminophen, and intravenous morphine sulfate on treatment of abdominal pain in patients with appendicitis: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of intravenous ibuprofen, intravenous acetaminophen, and intravenous morphine sulfate on treatment of abdominal pain in patients with appendicitis Design: A triple blind randomized clinical trial. Setting and conduct: The eligible patients with appendicitis who will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 60 years; appendicitis; beginning of abdominal pain within past 24 hours. Exclusion criteria: Pregnancy; using analgesic within past 6 hours; using antibiotic within past 24 hours; chronic abdominal disease; addiction to narcotic; a history of gastrointestinal bleeding; coagulopathy; using medications such as warfarin, lithium, furosemide, or ACEI. Intervention group 1: Intravenous infusion of ibuprofen 10 mg/kg plus 100 ml normal saline within 30 minutes. Intervention group 2: Intravenous infusion of morphine sulfate 0.1 mg/kg plus 100 ml normal saline within 30 minutes. Intervention group 3: Intravenous infusion of acetaminophen 10 mg/kg plus 100 ml normal saline within 30 minutes. Primary outcome: (a) assessing pain severity before intervention and 15, 30 and 60 minutes after intervention using Visual Analog Scale (VAS); (b) assessing nausea and vomiting before intervention and 15, 30 and 60 minutes after intervention through history taking. 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709279014N190**
Registration date: **2017-09-28, 1396/07/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-28, 1396/07/06

Registrant information

Name

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Name of organization / entity

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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

2017-10-07, 1396/07/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravenous ibuprofen, intravenous acetaminophen, and intravenous morphine sulfate on treatment of abdominal pain in patients with appendicitis: a triple blind randomized clinical trial

Public title
Comparison of the effect of intravenous ibuprofen, intravenous acetaminophen, and intravenous morphine sulfate on treatment of abdominal pain in patients with appendicitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age of 18 to 60 years; appendicitis; beginning of abdominal pain within past 24 hours. Exclusion criteria: Pregnancy; using analgesic within past 6 hours; using antibiotic within past 24 hours; chronic abdominal disease; addiction to narcotic; a history of gastrointestinal bleeding; coagulopathy; using medications such as warfarin, lithium, furosemide, or ACEI.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
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
Postal code
Approval date
2017-06-17, 1396/03/27
Ethics committee reference number
IR.UMSHA.REC.1396.245

Health conditions studied

1

Description of health condition studied
Appendicitis
ICD-10 code
K35
ICD-10 code description
Acute appendicitis

Primary outcomes

1

Description
Assessing pain severity
Timepoint
Before intervention and 15, 30 and 60 minutes after intervention
Method of measurement
Using Visual Analog Scale (VAS)

2

Description
Assessing nausea and vomiting
Timepoint
Before intervention and 15, 30 and 60 minutes after intervention
Method of measurement
Through history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Intravenous infusion of ibuprofen 10 mg/kg plus 100 ml normal saline within 30 minutes.

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous infusion of morphine sulfate 0.1 mg/kg plus 100 ml normal saline within 30 minutes.

Category

Treatment - Drugs

3

Description

Intervention group 3: Intravenous infusion of acetaminophen 10 mg/kg plus 100 ml normal saline within 30 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Hila Farokhpey Samami

Street address

Besat Hospital, Shahed Square

City

Hamadan

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

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

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

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

Besat Hospital

Full name of responsible person

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Full name of responsible person

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Other areas of specialty/work
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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