Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparisons between effect of intera venous Ibuprofen with Tramadol for prevention of postoperative shivering with general anesthesia

Protocol summary

Study aim
Comparative study of intravenous ibuprofen and tramadol in preventing shivering after abdominal surgery with general anesthesia
Design
Controlled clinical trial, community-based, parallel group, triple blind, randomized.
Settings and conduct
The present study was carried out with controlled clinical trials; triple blind on patients undergoing abdominal surgery (cholecystectomy and laparatomy) and under general anesthesia referring to Fatemi Hospital in the age range of 20 to 70 years old and on both males and females.
Participants/Inclusion and exclusion criteria
Inclusion criteria, eligible patients will be ASA1,2 physical. Severe cardiovascular disease, liver and kidney disorders, peptic ulcer, muscle disease, blood transfusions or blood products during surgery, or history of seizure, as well as surgeries with a duration of more than 2 hours as exclusion criteria.
Intervention groups
Tramadol 1 mg / kg and intravenous ibuprofen (800 mg ampoules) given in the same volume 30 minutes before surgery (injected over 10 minutes).
Main outcome variables
check in scale of shivering

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180615040104N1**
Registration date: **2018-10-01, 1397/07/09**
Registration timing: **retrospective**

Last update: **2018-10-01, 1397/07/09**
Update count: **0**
Registration date
2018-10-01, 1397/07/09

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-13, 1396/11/24
Expected recruitment end date
2018-08-21, 1397/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparisons between effect of intera venous Ibuprofen with Tramadol for prevention of postoperative shivering with general anesthesia

Public title
The effect of intravenous ibuprofen and tramadol on shivering after abdominal surgery with general anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing cholecystectomy (surgical) Male patients referred to Ardabil Fatemi Hospital in the range of 20 to 70 year. Female patients referred to Ardabil Fatemi Hospital in the range of 20 to 70 year.
Exclusion criteria:
Severe cardiovascular disease Liver and kidney disorders Peptic ulcer disease Muscular disease Patients with history of the blood transfusions or blood products during surgery Patients with history of seizure Surgeries with a duration of more than 2 hours

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into three groups. Initially, 120 envelopes will be prepared that 40 with letters (A) and 40 with letters (B) and 40 envelopes with letters (E) written. The drugs will be encoding, so that the injector And the checklist registrar is not aware of the quiddity of the codes. The drugs are drawn in two Session (in volume of 2 cc) and in the same color of the syringes and the code is recorded on them. The technician outside of the research group prepares drugs and the researcher does not know the quiddity of the codes, type of injectable drugs and drugs are injected according to the selected code. Then an envelope is randomly selected and the drug that containing the code in the envelope is injected to the patient and the results are recorded in the checklist.

Blinding (investigator's opinion)
Triple blinded

Blinding description
At first three boxes with codes A, B and C were prepared. Then the medications were given to an anesthetic technician. He was asked to place the vials of each drug in one of the boxes. Vials should be similar and without names. The packets are packed in each group and then the researcher randomly selects one of the envelopes and injects and records the results in checklists.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical University of Ardebil

Street address
No. 90, Mlek Ashtar Alley, Otobosrani St., Ardebil City

City
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Ardabil

Postal code
5619866111

Approval date
2018-02-17, 1396/11/28

Ethics committee reference number
IR. ARUMS. REC. 1396. 228

Health conditions studied

1

Description of health condition studied
Cholelithiasis, cholecystitis and other diseases associated with gallbladder

ICD-10 code
k808,182

ICD-10 code description
Calculus of gallbladder with acute cholecystitis, Calculus of gallbladder with other cholecystitis, Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description
check in scale of shivering

Timepoint
check in scale of post operative shivering based on observation muscle movement in recovery and scored

Method of measurement
score

Secondary outcomes

1

Description
check in scale of post operative nausea and vomiting and sedation and pain.

Timepoint
check in scale of post operative indication of nausea and vomiting and sedation and pain based on APFEL & RAMSAY score and VAS

Method of measurement
score

Intervention groups

1

Description
Interventions group1: Tramadol ampoule 1 mg / kg
Category
Prevention

2

Description
Interventions group2: intravenous ibuprofen ampoule 800 mg
Category
Prevention

3

Description
Control group: Placebo (normal saline with the same volume and shape with the intervention groups)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ardebil Fatemi Hospital
Full name of responsible person
Ghodrat Akhavan Akbari
Street address
University Ave.
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Sponsors / Funding sources

1

Sponsor
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Ghodrat Akhavan Akbari
Position
Pain Fellowship anesthesiologist.´
Latest degree
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Person responsible for updating data

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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