Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparisons between effect of Intravenous Paracetamol with Meperidine for prevention of postoperative shivering with general anesthesia

Protocol summary

Study aim
Prevention of postoperative shivering with general anesthesia
Design
A clinical trial randomized and triple blinded is performed on 120 patients
Settings and conduct
Field of study: Fatemi Hospital in Ardabil A trial triple blinded randomized clinical is done on 120 patients. Outcomes are measure of shivering, nausea, vomiting and postoperative pain
Participants/Inclusion and exclusion criteria
Inclusion criteria: patients undergoing cholecystectomy (surgical); male and female patients referred to Ardabil Fatemi Hospital in the range of 20 to 70 years Exclusion criteria: severe cardiovascular disease; Liver and Kidney disorders; peptic ulcer disease; muscular disease; patients with history of blood transfusions or blood products during surgery; patients with history of seizure; surgeries with a duration of more then 2 hours
Intervention groups
Interventions group 1: Intravenous Paracetamol ampoule 1 gr Interventions group 2: Meperidine ampoule 30 mg Control group: placebo(normal saline with the same volume and shape with the intervention
Main outcome variables
Check in scale of shivering

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180725040597N1**
Registration date: **2018-10-31, 1397/08/09**
Registration timing: **retrospective**

Last update: **2018-10-31, 1397/08/09**
Update count: **0**
Registration date
2018-10-31, 1397/08/09

Registrant information
Name
Sara Ezati
Name of organization / entity
Country
Iran (Islamic Republic of)
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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 Intravenous Paracetamol with Meperidine for prevention of postoperative shivering with general anesthesia

Public title
The effect of Intravenous Paracetamol and Meperidine on shivering after abdominal surgery with general anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing cholecystectomy (surgical) Patients referred to Ardabil Fatemi Hospital in the range of 20 to 70 years
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 then 2 hours

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Visitors are randomly divided into three groups, at first 120 envelopes have been prepared that containing 40 of them are written in letter A and 40th letter B and 40th letter C. Drugs are encoded so that the injector and the checklist completes are not aware of the nature of the codes. Medications are injected into the syringes in the same of volume and shape. Technician prepares medication and the researcher did not know the nature of the codes and type of drug. An envelope is selected randomly and injected drug inside of packet then the results are recorded in checklist,

Blinding (investigator's opinion)
Triple blinded

Blinding description
At first three boxes with 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 selected one of the envelopes and injects and records results in checklist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardebil University of Medical Sciences

Street address
No. 35/1, West Eslami3., Street Moallem

City
Ardebil

Province
Ardabil

Postal code
5613633681

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

Ethics committee reference number
IR. ARUMS. REC. 1396. 229

Health conditions studied

1

Description of health condition studied
cholelitiasis and cholesystitis and other disease associated with gallbladder

ICD-10 code
K808, 182

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

Primary outcomes

1

Description
Check in scale of shivering

Timepoint
Measurement at times 5, 15 minutes after entering the recovery

Method of measurement
Shivering Grading

Secondary outcomes

1

Description
check in scale of postoperative sedation

Timepoint
Measurement at times 5, 15 minuets after entering the recovery

Method of measurement
Ramsay scale

Intervention groups

1

Description
Intervention group: Intravenous Paracetamol ampoule 1gr

Category
Prevention

2

Description
Intervention group: Intravenous Mepridin ampoule 30 mg
Category
Prevention

3

Description
Control group: Normal Saline ampoule with the same of volume and forme.
Category
Placebo

Recruitment centers

1

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

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Deputy of research and technology
Street address
University Ave.
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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
Godrat Akhavan Akbari
Position
Associate professor
Latest degree
Subspecialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

Age,sex and other personal information

When the data will become available and for how long

2018/10/01

To whom data/document is available

Whole of Professors in university

Under which criteria data/document could be used

Whole of Professors in university

From where data/document is obtainable

Ardabil university of science

What processes are involved for a request to access data/document

Take a permit from university

Comments