

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 than 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)

Phone

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Email address

s.ezati@arums.ac.ir

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	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
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	Health conditions studied <u>1</u> Description of health condition studied cholelithiasis and cholecystitis 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 cholecystitis, calculus of gallbladder without cholecystitis
Secondary Ids empty Ethics committees <u>1</u> Ethics committee	Primary outcomes <u>1</u> Description Check in scale of shivering Timepoint Measurement at times 5, 15 minutes after entering the recovery Method of measurement Shivering Grading Secondary outcomes <u>1</u> 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 <u>1</u> 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

Fatemi Hospital, Street Shaiati

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Ardabil

Province

Ardabil

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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

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University Ave.

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Province

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Fax**Email**

research@arums.ac.ir

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

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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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