Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectivness of intravenous Acetaminophen and Ondansetron in prevention of postappendectomy shivering in general anesthesia method

Protocol summary

Study aim
Effectivness of intravenous acetaminophen and ondansetron in prevention of postappendectomy shivering

Design
A randomized,blinded,sham controlled clinical trial with a parallel group design of 150 patients,in 3group includ acetaminophen,ondansetron and plasebo

Settings and conduct
150 Patients undergoing apendectomy surgery study randomly into three groups includ Acetaminophen,Ondansetron and Plasebo.Patients are not aware of the type of medication they receive.The method of randomization will be closed packed packages.For random allocation drugs in 3 group will be prepared every morning befor surgery by the presenter50 packet in 3 group A,B,C will chosen by nonaware person(Anesthetic technician)and will be injected to patients by Anesthetic Resident.In Acetaminophen group 15mg/kg and 8mg Ondansetron in Ondansetron group and 2cc Normal Salin in Plasebo group will be injected.Injectable solution volume in 3group will be equal(2cc).Post Operative shivering will be asked by Medicine Intern and pain and vomiting will be asked in recovery room and recorded in questionnaire.

Participants/Inclusion and exclusion criteria
Satisfaction to enter the study,Age between15_55,Class ASA I, II,exit requirement of study, History of allergy to acetaminophen or ondansetron,Rynod syndrom,Hypothyroid,Hyperthyroid,Cardiovascular disease,psychologic disease,body temprature>38or<36

Intervention groups
15mg/kg up to 1gr acetaminophen and 8 mg ondansetron and 2 cc normal salin

Main outcome variables
Postoperative shivering

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190226042852N1**
Registration date: **2019-07-27, 1398/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-27, 1398/05/05**
Update count: **0**

Registration date
2019-07-27, 1398/05/05

Registrant information

Name
Asra Fathollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 4212 2064

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-11, 1398/04/20

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effectivness of intravenous Acetaminophen and Ondansetron in prevention of postappendectomy shivering in general anesthesia method

Public title
Effectivness of intravenous Acetaminophen and Ondansetron in prevention of shivering

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction to enter the study Age between15_55 Class ASA I, II

Exclusion criteria:
Exit requirement of study History of allergy to Acetaminophen or Ondansetron Rynaud syndrom Hypothyroid or Hyperthyroid Cardiovascular disease Body temprature>38or<36

Age
From **15 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Convenience sampling determines the inclusion of patients to this study.These patients will be randomly investigated in 3 groups of Acetaminophen,Ondansetron and Placebo.Closed packets will be employed as randomization tool in this study.To randomize 3packs of A,B and C will be prepared based on the sample size and randomly injected to the patients while considering the pack codes.Prepartion of these 3medicines will be done by an anesthetic technician not having any part in the research and then rendered for injection by a person who is unaware of the syringe content.In Acetaminophen group 15mg/kg and 8mg Ondansetron in Ondansetron group and 2cc Normal Salin in placebo group will be injected.To apply blinding,Solution for injection will contain an equal volume of2cc for all the three groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Preparation of drugs will be done by Anesthetic technician who is no role in this study and injection will be done by person who nonaware of syringe matter.In Acetaminophen group 15mg/kg and 8mg Ondansetron in Ondansetron group and 2cc Normal Salin in plasebo group will be injected.Injectable solution volume in 3group will be equal(2cc).Another person who nonaware of type of injected drugs,evaluated patients post operative.Person who analize data not be aware of type of injected drugs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardabil University ofMedical Sciences

Street address
university street,Ardabil

City
Ardabil

Province
Ardabil

Postal code
۵۶۱۸۹-۸۵۹۹۱

Approval date
2018-02-18, 1396/11/29

Ethics committee reference number
IR.ARUMS.REC.1396.255

Health conditions studied

1

Description of health condition studied
Effectivness of acetaminophen and ondansetron in prevention ofshivering

ICD-10 code
T88.5

ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
shivering

Timepoint
Postoperative

Method of measurement
grading of shivering

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intravenous Acetaminophen
Category
Treatment - Drugs

2

Description
Intervention group: Intravenous ondansetron
Category
Treatment - Drugs

3

Description
Control group: Normal salin
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Fatemi Hospital
Full name of responsible person
Asra Fathollahi
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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
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consultant
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available