

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

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

#### Protocol summary

##### Study aim

Effectiveness 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 3 groups including acetaminophen, ondansetron and placebo

##### Settings and conduct

150 Patients undergoing appendectomy surgery study randomly into three groups including Acetaminophen, Ondansetron and Placebo. 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 groups will be prepared every morning before surgery by the presenter. 50 packets in 3 groups A, B, C will be chosen by a non-aware 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 Saline in Placebo group will be injected. Injectable solution volume in 3 groups 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 between 15\_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 temperature >38 or <36

##### Intervention groups

15mg/kg up to 1gr acetaminophen and 8 mg ondansetron and 2 cc normal saline

##### 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)

##### Phone

+98 41 4212 2064

##### Email address

asra.fathollahi@arums.ac.ir

##### 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

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

#### Public title

Effectiveness of intravenous Acetaminophen and Ondansetron in prevention of shivering

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Satisfaction to enter the study Age between 15\_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 >38 or <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 3 packs of A, B and C will be prepared based on the sample size and randomly injected to the patients while considering the pack codes. Preparation of these 3 medicines 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 of 2cc 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 placebo group will be injected. Injectable solution volume in 3 group will be equal (2cc). Another person who nonaware

of type of injected drugs, evaluated patients post operative. Person who analyze 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 of Medical 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

Effectiveness of acetaminophen and ondansetron in prevention of shivering

#### 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 saline

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Dr Fatemi Hospital

#### Full name of responsible person

Asra Fathollahi

#### Street address

Dr Fatemi Hospital, Shariati street, Ardabil

#### City

Ardabil

#### Province

Ardabil

#### Postal code

5614733775

#### Phone

+98 45 3323 2520

#### Fax

+98 45 3323 2670

#### Email

Fatemi@arums.ac.ir

#### Web page address

<http://www.arums.ac.ir/fatemi/fa>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ardabil University of Medical Sciences

#### Full name of responsible person

Dr Shahab Bohlooli

#### Street address

University street, Ardabil

#### City

Ardabil

### Province

Ardabil

### Postal code

8599156189

### Phone

+98 45 3352 2391

### Fax

+98 45 3353 4773

### Email

s.bohlooli@pharmacy.arums.ac.ir

### Web page address

<http://www.arums.ac.ir/fa>

### 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

Dr Hamed Zandian

#### Position

consultant

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Others

#### Street address

university street, Ardebil university medicine science

#### City

Ardebil

#### Province

Ardabil

#### Postal code

8599156189

#### Phone

+45 33 52 22 47

#### Fax

+98 45 3353 4773

#### Email

h.zandian@arums.ac.ir

#### Web page address

<http://academic.arums.ac.ir/h-zandian/fa>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Ahmad Ghazi

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

University street

**City**

Ardebil

**Province**

Ardabil

**Postal code**

8599156189

**Phone**

+98 224733524498

**Fax**

+98 45 3353 4773

**Email**

a.ghazi@arums.ac.ir

**Web page address**

<http://www.arums.ac.ir/medicine/fa>

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Asra Fathollahi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Anesthesiology

**Street address**

shahid beheshti street,zonouz

**City**

zonouz

**Province**

East Azarbaijan

**Postal code**

5436119536

**Phone**

+98 41 4212 2064

**Fax**

+98 45 3353 4773

**Email**

asra.fathollahi@arums.ac.ir

**Web page address**

<http://www.arums.ac.ir/fa>

## 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