

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Clinical trial of comparison of Ondansetron and Metoclopramide effect on postoperative nausea and vomiting in patients with appendicitis and cholecystitis

#### Protocol summary

##### Summary

Objective: Comparing the efficacy of Ondansetron and Metoclopramide in the treatment of nausea and vomiting after appendectomy and cholecystectomy. Design and setting: A randomized; double-blind; clinical trial study; single center; clinical trial phase 3. In this study, 90 samples were selected and allocated into two intervention and control groups using block randomization method during 12 months. Inclusion criteria: patients with appendicitis and cholecystitis that needs to surgery; ASA I or II; Age between 15 to 70 years old and approve to participate in study. Exclusion criteria: Unstable hemodynamic; recent use of antiemetic drugs; allergy to Metoclopramide and Ondansetron. Intervention: Control group received 15 mg Metoclopramide, single dose intravenously. Intervention group received 1 mg/kg Ondansetron, single dose intravenously. If the need analgesic, Diclofenak with 75 mg/IM is using. Main outcome measures: 1) Nausea severity assessment at 1,6,12 and 24 hours after the drug injection using visual analogue scale; 2) Number of vomiting episodes from 1,6,12 and 24 hours after drug injection; 3) Need for excessive drug to reduce nausea and vomiting 1 hour after injection; 4) Adverse effects of drugs

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201601232954N8**

Registration date: **2017-10-21, 1396/07/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-21, 1396/07/29

##### Registrant information

###### Name

Mohammad Bagher Sohrabi

###### Name of organization / entity

Shahroud University of Medical Ssciences and Health

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 5054

###### Email address

mb.sohrabi@shmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2017-09-23, 1396/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of comparison of Ondansetron and Metoclopramide effect on postoperative nausea and vomiting in patients with appendicitis and cholecystitis

##### Public title

The comparison of Ondansetron and Metoclopramide effect on postoperative nausea and vomiting

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: patients with appendicitis and cholecystitis that needs to surgery; ASA I or II; age between 15 to 70 years old; Patients satisfaction on participation in the study. Exclusion criteria: Systolic blood pressure lower than 90 mmHg; Unstable hemodynamic; Opium addiction; history of uncontrolled diseases (Parkinson, Restlessness syndrome, Epilepsy, GI bleeding, Pheochromocytoma); Recent use of CNS depressant drugs; Recent use of antiemetic drugs; allergy to the drugs used in this study

## **Age**

From **15 years** old to **70 years** old

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **90**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

In this study the randomization was conducted with block randomization method .

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Azad Islamic University, Shahroud Branch

##### **Street address**

Azad Islamic University, Shahroud

##### **City**

Shahroud

##### **Postal code**

3615111151

#### **Approval date**

2014-11-16, 1393/08/25

#### **Ethics committee reference number**

93/231

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Appendicitis

#### **ICD-10 code**

K35

#### **ICD-10 code description**

Acute appendicitis

### 2

#### **Description of health condition studied**

Cholecystitis

#### **ICD-10 code**

K81

#### **ICD-10 code description**

Cholecystitis

### 3

#### **Description of health condition studied**

Nausea and vomiting

#### **ICD-10 code**

R11

#### **ICD-10 code description**

Nausea and vomiting

## **Primary outcomes**

### 1

#### **Description**

Nausea severity

#### **Timepoint**

1, 6,12 and 24 hours after surgery

#### **Method of measurement**

Visual Analogue Scale

### 2

#### **Description**

Number of vomiting

#### **Timepoint**

1, 6,12 and 24 hours after surgery

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Pain severity

#### **Timepoint**

1 hour after surgery to 24 hours

#### **Method of measurement**

Visual Analogue Scale

### 2

#### **Description**

Need to excessive drugs

#### **Timepoint**

1 hour after surgery to 24 hours  
**Method of measurement**  
Observation

## Intervention groups

### 1

#### Description

Intervention: These patients receive 1 milligram per kg Ondansetron(made in Shahredaru Pharmaceutical Company in Islamic Republic Of Iran) single dose;intravenously.

#### Category

Treatment - Drugs

### 2

#### Description

These patients receive 15 milligram Metoclopramide (made in Osveh Pharmaceutical Company in Islamic Republic Of Iran) single dose; intravenously.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein hospital

##### Full name of responsible person

Dr. Mehdi Ebrahimi

##### Street address

Imam Hossein hospital ,Shahroud , Iran

##### City

Shahroud

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Azad Islamic University, Shahroud Branch

##### Full name of responsible person

Dr. Abbasali Manafi

##### Street address

Azad Islamic University, Shahroud

##### City

Shahroud

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Azad Islamic University, Shahroud Branch

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shahroud University of Medical science

##### Full name of responsible person

Dr.Mohammad Bagher Sohrabi

##### Position

General Practitioner

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*