

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

Shahroud University medical Sciences ,7th Tir squar, Shahroud

City

Shahroud

Postal code

3615111151

Phone

+98 23 3239 5054

Fax

+98 23 3239 4800

Email

mb.sohrabi@yahoo.com; mb.sohrabi@shmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical science

Full name of responsible person

Dr. Mehdi Ebrahimi

Position

General Surgion

Other areas of specialty/work

Street address

Imam Hossein hospital, Shahroud, Iran

City

Shahroud

Postal code

3615111151

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

drmebrahimi@shmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical science

Full name of responsible person

Dr.Mehdi Ebrahimi

Position

General Sergion

Other areas of specialty/work**Street address**

Imam Hossein hospital, Shahroud, Iran

City

Shahroud

Postal code

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+98 23 3234 2000

Fax

+98 23 3233 3902

Email

drmebrahimi@shmu.ac.ir

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