

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The efficacy of Ondansetron and Granisetron in preventing of post Laparoscopic Cholecystectomy nausea and vomiting (PONV)

#### Protocol summary

##### Study aim

Comparison of Ondansetron and Granisetron Effects in the Prevention of Nausea and Vomiting in Patients Subjected to Laparoscopic Cholecystectomy Surgery

##### Design

Two arm parallel group randomized clinical trial, double blind

##### Settings and conduct

This study was non-control group with two groups receiving Ondansetron and Granisetron. This study was conducted at Shahid Mohammadi Hospital in Bandar Abbas.

##### Participants/Inclusion and exclusion criteria

Conditions for entering the study in a patient aged between 18-60 years with ASA I, II candidate for laparoscopic cholecystectomy who referred to Shahid Mohammadi Hospital in 1396-1393, and criteria for withdrawal, febrile illness, history of infection Pulmonary disease, Allergy to Endonestrone and Granisetron, pregnancy, inability to perceive VAS criteria for pain, The patient's consent for participation in the study was more than 120kg or less than 50kg.

##### Intervention groups

Patients were randomly divided into 2 groups. In a group of patients, 2 mg of Granisetron and another group received 4 mg of Endonestrone (in a total volume of 10 ml) 5 minutes before induction of anesthesia.

##### Main outcome variables

nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170101031697N2**

Registration date: **2019-06-25, 1398/04/04**

Registration timing: **retrospective**

Last update: **2019-06-25, 1398/04/04**

Update count: **0**

##### Registration date

2019-06-25, 1398/04/04

##### Registrant information

###### Name

Afshin Parvizpanah

###### Name of organization / entity

Hormozgan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 3333 6625

###### Email address

afshin.parvizpanah@hums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

2016-03-21, 1395/01/02

##### Actual recruitment end date

2018-01-22, 1396/11/02

##### Trial completion date

2018-02-21, 1396/12/02

##### Scientific title

The efficacy of Ondansetron and Granisetron in preventing of post Laparoscopic Cholecystectomy nausea and vomiting (PONV)

##### Public title

The efficacy of Ondansetron and Granisetron in preventing of post Laparoscopic Cholecystectomy nausea and vomiting

##### Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with ASA grade one Patients with ASA grade two Patient were referred for laparoscopic cholecystectomy

### Exclusion criteria:

Febrile illness History of infection Pulmonary disease Allergy to Endonestrone Allergy to Granisetron History of seizure History of vascular contraction Intracranial pressure History of drug abuse Patients who do not have proper collaboration during the study History of digestive disease Emergency patients Patients with a history of motion sickness (PTSD) or motion sickness (PONV) have a history of nausea and vomiting Surgery Patients with history of nausea and vomiting during previous surgery Patients who received anti-nausea and vomiting before surgery Patients with hypothermia (below 36 ° C) Pregnancy Inability to perceive VAS criteria for pain The patient's consent for participation in the study Weight more than 120kg Weight less than 50kg

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **90**

Actual sample size reached: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After identifying the patients, patients were randomly assigned to the study groups. Randomization was carried out in a sub-unit using statistical software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The pump syringes were prepared by an expert in the anesthetic room and the assistant did not know its content.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics Committee of Bandar Abbas University of Medical Sciences

### Street address

Ethics Committee of Bandar Abbas University of Medical Sciences, Research Deputy Building, Shahid Mohammadi Hospital, Jomhoori Islami Blvd.

### City

Bandar Abbas

### Province

Hormozgan

### Postal code

7916613885

### Approval date

2017-09-20, 1396/06/29

### Ethics committee reference number

IR.HUMS.REC.1394.120

## Health conditions studied

### 1

#### Description of health condition studied

nausea and vomiting

#### ICD-10 code

R11

#### ICD-10 code description

Nausea and vomiting

## Primary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

Patients were monitored for nausea and vomiting during recovery and after recovery for 24 hours during the hours (2-4-6-12-24).

#### Method of measurement

According to Clinical Obstetrician Anesthesiologist.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: Patients in this group received 2 mg of Granisetron (in a total volume of 10 ml), 5 minutes before induction of anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

Second intervention group: Patients in this group received 4 mg of Ondansetron (in a total volume of 10 ml), 5 minutes before induction of anesthesia.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Mohamadi hospital, Bandar Abbas;IRAN

**Full name of responsible person**

Said Kashani

**Street address**Shahid Mohammadi Hospital, Jomhuri Islami St,  
Imam Khomeini Blvd**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3334 5009

**Email**

Sdkashani486@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Teamour Aghamolai

**Street address**Shahid Mohammadi Hospital, Jomhuri Islami St,  
Imam Khomeini Blvd**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3334 5009

**Email**

taghamolaei@hums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Said Kashani

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**Department of Anesthesiology , Shahid Mohammadi  
Hospital, Jomhuri Islami St, Imam Khomeini Blvd**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3334 5009

**Email**

Sdkashani486@gmail.com

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

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Said Kashani

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**Department of Anesthesiology , Shahid Mohammadi  
Hospital, Jomhuri Islami St, Imam Khomeini Blvd**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3334 5009

**Email**

Sdkashani486@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Said Kashani

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Department of Anesthesiology , Shahid Mohammadi  
Hospital, Jomhourī Islami St, Imam Khomeini Blvd

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3334 5009

**Email**

Sdkashani486@gmail.com

## 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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

SPSS file

**When the data will become available and for how long**

5/17/2019

**To whom data/document is available**

Researchers and referees

**Under which criteria data/document could be used**

Obtaining a written permit and mentioning the name in the sources

**From where data/document is obtainable**

Dr. Saeed Kashani Sdkashani486@gmail.com

**What processes are involved for a request to access data/document**

Email your request.

**Comments**