Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of Ondansetron and Granisetron in preventing of post Laparascopic Cholesystectomy 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 ASAI, 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)

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+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 Laparascopic Cholesystectomy nausea and vomiting (PONV)

Public title
The efficacy of Ondansetron and Granisetron in preventing of post Laparascopic Cholesystectomy 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, Jomhouri Islami St, Imam Khomeini Blvd
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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, Jomhouri Islami St, Imam Khomeini Blvd
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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
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
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Person responsible for updating data

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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