# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Camparison of the effect of ondansetron and placebo versus ondansetron and aprepitant on post-operation nausea and vomitiing of cholecystectomy surgery

## Protocol summary

**Study aim**

The aim of this study is to determine the effect of ondansetron and placebo versus ondansetron and aprepitant on nausea and vomiting after cholecystectomy surgery. If the combination of aprepitant and ondansetron has a greater effect on nausea and vomiting, this method can be used as an auxiliary treatment in the treatment of postoperative nausea and vomiting.

**Design**

A clinical trial with a control group, with parallel groups, double-blind, randomized by block randomization method, phase 2 on 60 patients.

**Settings and conduct**

Patients undergoing cholecystectomy at Shahid Modares Hospital in Tehran between 2020 to 2021. This study is conducted in a double-blind manner. A nurse not involved in the study codes the drugs, the person who prescribes the drug, and those who collect information from the patients after the procedure are blinded. Nausea and vomiting of patients are evaluated 6 and 24 hours after the end of the operation.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: All patients between the ages of 18 and 50 years old with a 1 or 2 score on the ASA health scale, are candidates for cholecystectomy surgery. Exclusion criteria: patients with a 3, 4, or 5 score on the ASA health scale; Patients undergoing cholecystectomy with another anesthesia method; patients suffering from any systemic disease, People addicted to alcohol, drugs, and smoking; Acute cholecystitis.

**Intervention groups**

Control group: At the same time as the operation, 4 mg of ondansetron is administered intravenously and a placebo capsule is administered one hour before the operation. Intervention group: Aperpitant capsule of 80 mg one hour before the operation, and at the same time as the operation, ondansetron 4 mg is administered intravenously.

**Main outcome variables**

Nausea and vomiting after the operation

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20221110056459N1**
Registration date: **2023-09-21, 1402/06/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-21, 1402/06/30**
Update count: **0**

**Registration date**

2023-09-21, 1402/06/30

**Registrant information**

**Name**

Maryam Abbasi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2207 4087

**Email address**

maryamabbasi@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-03-21, 1402/01/01

**Expected recruitment end date**

2024-04-19, 1403/01/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Camparison of the effect of ondansetron and placebo versus ondansetron and aprepitant on post-operation nausea and vomitiing of cholecystectomy surgery

**Public title**

effect of aprepitant on post-operation nausea vomiting of cholecystectomy surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

patients with ASA health scale of 1 or 2 patients who are candidated for cholecystectomy surgery

**Exclusion criteria:**

patients with ASA health scale of 3, 4 or 5 patients with other anesthesia methods patients with any systemic diseases such as diabetes, asthma, cardiovascular diseases, gastroesophageal reflux, severe obesity, BMI > 30, hepatorenal diseases, neuromuscular diseases, psychiatric illnesses, alcoholic patients, drug abusers, smokers pregnant or lactating patients patients presented with acute cholecystitis

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method assigns Patients to one of the intervention and control groups. The randomization method is based on random blocks of four. In this way, each study group is assigned code A or B, and different blocks of four were made by https://www.sealedenvelope.com/ website. Then patients were assigned to different blocks based on the order of entering the trial.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Medications are coded by a nurse who is not participating in the study. The person who prescribes the medicine also does the prescription without knowing the type of medicine. In the recovery and inpatient ward, colleagues collect information without knowing the type of drug received and the groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

department of general surgery, Shahid Modarres hospital, Saadat Abad intersection, Yadegar Imam Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1998734383

**Approval date**

2022-05-24, 1401/03/03

**Ethics committee reference number**

IR.SBMU.MSP.REC.1401.116

## Health conditions studied

### 1

**Description of health condition studied**

Nausea

**ICD-10 code**

R11.0

**ICD-10 code description**

Nausea

### 2

**Description of health condition studied**

vomiting

**ICD-10 code**

R11.1

**ICD-10 code description**

Vomiting

## Primary outcomes

### 1

**Description**

The degree of nausea

**Timepoint**

6 and 24 hour post-operation

**Method of measurement**
VAS criteria

**2**

**Description**
vomiting
**Timepoint**
6 and 24 hour post-operation
**Method of measurement**
if vomiting happen or not

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Aperpitant capsule 80 mg is prescribed one hour before the operation, and at the same time as the anti-nausea drug ondansetron 4 mg is administered intravenously.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: At the same time as the operation, the anti-nausea drug ondansetron 4 mg is administered intravenously and a placebo capsule is administered one hour before the operation.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Modarres hospital
**Full name of responsible person**
Seyed Hassan Fatemi
**Street address**
General surgery department, Shahid Modarres Hospital, Saadat Abad Intersection, Yadegar Imam Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1998734383
**Phone**
+98 21 2207 4087
**Email**
modarres@sbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Dr. Afshin Zarghi
**Street address**
Fifth Floor, Building No. 2, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1985717443
**Phone**
+98 21 2243 9780
**Email**
info@sbmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Nasser Malekpour Alamdari
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
General Surgery
**Street address**
General surgery department, Shahid Modarres Hospital, Saadat Abad Intersection, Yadegar Imam Highway
**City**
Tehran
**Province**
Tehran

**Postal code**
1998734383
**Phone**
+98 21 2207 4087
**Email**
nassermalekpour@sbmu.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Nasser Malekpour Alamdari
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
General Surgery
**Street address**
General surgery department, Shahid Modarres Hospital, Saadat Abad Intersection, Yadegar Imam Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1998734383
**Phone**
+98 21 2207 4087
**Email**
nassermalekpour@sbmu.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Maryam Abbasi
**Position**
Assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
General Surgery
**Street address**
General surgery department, Shahid Modarres Hospital, Saadat Abad Intersection, Yadegar Imam Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1998734383
**Phone**
+98 21 2207 4087
**Fax**
**Email**
maryamabbasi1986@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**
Yes - There is 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**
Individual data of participants and information on the main outcome, and the final report of the trial will be presented in an international article. Also, more detailed information will be accessible to researchers in coordination with the correspondence.
**When the data will become available and for how long**
The access period starts 6 months after the results are published.
**To whom data/document is available**
researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
All researchers working in academic and scientific institutions can send their request by mentioning the reason. The use of data and results of this clinical trial for personal and commercial purposes is not allowed.
**From where data/document is obtainable**
Dr. Nasser Malekpour Alamdari: nassermalekpour@sbmu.ac.ir Dr. Maryam Abbasi: maryamabbasi1986@gmail.com
**What processes are involved for a request to access data/document**
After sending the request to the given addresses, the responsible persons will check the cases and after inquiring the identity of the requester, they will send the documents to them. This process may take up to a month.
**Comments**