

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The Comparison of two combination of dexamethasone and ondansetron with dexamethasone and plasil on Nausea, vomiting and chills in patients undergoing laparoscopic cholecystectomy

#### Protocol summary

##### Summary

This study is a double-blind randomized clinical trial, on 100 patients, with the aim of survey two combination of dexamethasone and ondansetron with dexamethasone and Plasil on nausea and vomiting, shivering in patients undergoing laparoscopic cholecystectomy will be done. Inclusion criteria including Biliary colic pain and Having indication to laparoscopy cholecystectomy and exclusion criteria included conversion to open Cholecystectomy and complicated cholecystitis. Patients randomly with using random numbers table will be divided into two groups of 50 Patients to the first group 8mg IV dexamethasone+ ondansetron and to second group 8mg dexamethasone+ 10mg plasil will be injected. Anesthesia and drugs used for anesthesia will be the same for both groups. After end of surgery, unaware questioner will be question from patient up to 24 hours after operation (at 1,6,12 and 24 hours) about primary outcome chills, nausea, vomiting and Secondary outcomes that is including dizziness and headaches and answers to the questionnaire will be recorded. The nausea and vomiting patients be evaluated through a N & V scoring. Chills will be graded score of 0-4.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017010923559N7**  
Registration date: **2017-03-20, 1395/12/30**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-03-20, 1395/12/30

#### Registrant information

##### Name

Somaieh Matin

##### Name of organization / entity

Ardabil University of Medicine Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3373 3011

##### Email address

s.matin@arums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

#### Expected recruitment start date

2017-03-21, 1396/01/01

#### Expected recruitment end date

2017-09-22, 1396/06/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Comparison of two combination of dexamethasone and ondansetron with dexamethasone and plasil on Nausea, vomiting and chills in patients undergoing laparoscopic cholecystectomy

#### Public title

The Comparison of two combination of dexamethasone and ondansetron with dexamethasone and plasil on Nausea, vomiting and chills

#### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: Biliary colic pain, Uncomplicated gallstone, Consent to participate in the study. Exclusion criteria: Medical complications, sensitivity to dexamethasone, ondansetron and Plazil, complicated cholecystectomy, Open surgery is indicated for gallstones, lack of consent to participate in the study.

### **Age**

From **18 years** old to **65 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **100**

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

Randomized

### **Randomization description**

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

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

This study is double-blind. In this study, we have 2 types of envelopes. Envelopes A is containing dexamethasone and ondansetron and Envelopes B which contains dexamethasone and Plazil. Patients by executing and by table of random numbers divided into two A & B groups. According to Patient group, Envelopes For drugs injection will be delivered to anesthesia technician. Anesthesia technician does not know the type of injected drug.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

Ethics committee of Ardabil University of Medical Sciences

##### **Street address**

Daneshgah Ave, Ardabil University of Medical Sciences.

##### **City**

Ardabil

##### **Postal code**

5618985991

##### **Approval date**

2016-10-11, 1395/07/20

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

IR.ARUMS.REC.1395.52

## **Health conditions studied**

### 1

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

Cholecystectomy

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

K80.0

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

Calculus of gallbladder with acute cholecystitis

## **Primary outcomes**

### 1

#### **Description**

Nausea

#### **Timepoint**

Within 24 hours of operation

#### **Method of measurement**

Through a score of N & V.

### 2

#### **Description**

Vomit

#### **Timepoint**

Within 24 hours of operation

#### **Method of measurement**

Through a score of N & V.

### 3

#### **Description**

shivering

#### **Timepoint**

Within 24 hours of operation

#### **Method of measurement**

shivering visual scale

## **Secondary outcomes**

### 1

#### **Description**

Dizziness

#### **Timepoint**

Within 24 hours of operation

#### **Method of measurement**

question of patient

### 2

#### **Description**

Headache

#### **Timepoint**

Within 24 hours of operation

#### **Method of measurement**

MDAS questionnaire

## Intervention groups

### 1

#### Description

The first group received Intravenous dexamethasone (8 mg) and Intravenous ondansetron during surgery.

#### Category

Prevention

### 2

#### Description

The second group received Intravenous dexamethasone (8 mg) and Intravenous Plasil (10 mg) during surgery.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Masoud Entezari MD

##### Street address

Imam Khomeini Hospital, Shahid Ghafour Jeddi St,  
Ardabil

##### City

Ardabil

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Ardabil University of  
Medical Sciences

##### Full name of responsible person

Shahram Habibzadeh M.D. Deputy of Research and  
Technology

##### Street address

Vice chancellor for research, Ardabil University of  
Medical Sciences, Daneshgah St, Ardabil.

##### City

Ardabil

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Ardabil University of Medical  
Sciences

#### 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

Ardabil University of Medical Sciences

##### Full name of responsible person

Masoud Entezari Aal

##### Position

Professor, Department of Anesthesiology

##### Other areas of specialty/work

##### Street address

Imam Khomeini Hospital, Shahid Ghafour Jeddi St,  
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##### Postal code

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##### Phone

+98 45 3225 1688

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##### Email

m.entezari@arums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Masoud Entezari Aal

##### Position

Professor, Department of Anesthesiology

##### Other areas of specialty/work

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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*