

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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

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Full name of responsible person

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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