

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of premeditation clonidine on hemodynamic response to endotracheal intubation and carbon dioxide pneumoperitoneum (insufflation) and scale of postoperative shivering in patients undergoing laparoscopic cholecystectomy

Protocol summary

Summary

The purpose of the study :effects of oral clonidine in hemodynamic response to endotracheal intubation and carbon dioxide pneumoperitoneum (insufflation) and postoperative shivering in patients undergoing laparoscopic cholecystectomy based on age, sex, weight patients inclusion criteria : patients undergoing laparoscopic cholecystectomy; the age range 18 -70 years; On both the male and female exclusion criteria :having hypertension, hypotension, morbid obesity, severe hepatitis, endocrine diseases, kidney diseases, heart diseases the study population :all patients undergoing laparoscopic cholecystectomy surgery referring to Imam Khomeini hospital in ardebil. Sample size :60 patients (30 cases and 30 controls)of the total patients for simple random sampling randomly selected and checked. Patients were randomly assigned to two experimental and control groups were blocked and divided and patients in the case group 150 microgram tablet oral clonidine and in the control group 100 milligram vitamin C received and results are recorded in check list. In case of hemodynamic changes such as bradycardia or hypertension interventions and heart rate and mean arterial blood pressure and postoperative shivering in the case registered :1-baseline vital signs 2-before Laryngoscopy 3-after tracheal intubation (intervals of 1to 5 minutes)4-before blowing carbon dioxide 5-5 minutes after blowing carbon dioxide 6-15 minutes after blowing carbon dioxide 7-30 minutes after blowing carbon dioxide 8-evaluation of postoperative shivering score is based on the observation of muscle recovery and shivering patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022716612N4**

Registration date: **2016-06-07, 1395/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-07, 1395/03/18

Registrant information

Name

Khatereh Isazadehfar

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1225 1693

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kh.isazadehfar@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of premeditation clonidine on hemodynamic response to endotracheal intubation and carbon dioxide pneumoperitoneum (insufflation) and scale of postoperative shivering in patients undergoing laparoscopic cholecystectomy

Public title

Effects of oral clonidine on blood pressure and postoperative shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : patients undergoing laparoscopic cholecystectomy ; the age range 18_70 years ; on both the male and female Exclusion criteria:having hypertension ; hypotension; morbid obesity; severe hepatitis; endocrine diseases; kidney diseases; heart diseases

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical university of ardebil

Street address

ardebil

City

ardebil

Postal code

Approval date

2015-12-19, 1394/09/28

Ethics committee reference number

IR. ARUMS.REC.1394.69

Health conditions studied

1

Description of health condition studied

cholecystectomy laparoscop

ICD-10 code

k80 k81 k8

ICD-10 code description

cholelithiasis,cholecystitis,other deases of gallbladder

Primary outcomes

1

Description

change of blood pressure and heart rate

Timepoint

Before starting surgery and before Laryngoscopy and immediately after tracheal intubation and every 1_5 minutes before blowing carbon dioxide and 5,15 and 30 minutes after the blowing of carbon dioxide gas

Method of measurement

mm hg_counting heart beats

Secondary outcomes

1

Description

check in scale of shivering

Timepoint

check in scale of postoperative shivering based on observation muscle movement recovery and scored

Method of measurement

score

Intervention groups

1

Description

Group intervention : tab oral clonidine 150 microgram

Category

Prevention

2

Description

Group control : oral vitamin C 100 miligram

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Masaud Entezariasl

Street address

Ardebil

City

Ardebil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr.Akbar Pirzadeh

Street address

Ardebil. Imam Khomeini hospital

City

Ardebil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardebil 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

Dr.Masaud Entezari

Position

Anesthesiologist

Other areas of specialty/work

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inquiries

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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