Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, sever hepatitis, endocrine deases, kidney deases, 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

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Name of organization / entity
Ardabil University of Medical Sciences
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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; sever 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
cholelitihiasis,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
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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