Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Studying effect of Dexmedetomidine on postoprative Nausea & Vomiting(PONV)In Laparascopic Cholecystectomy in Addict patient

Protocol summary

Study aim

effect of dexmedetomidine(DEX) on postoperative nausea & vomiting(ponv) in laparoscopic cholecystectomy in addicted patients

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 100 patients, patients with aspect ratio (1:1), receiving DEX or placebo, according to the random number generation table

Settings and conduct

100 addicted patients, laparoscopic cholecystectomy ,Shohadaye Tajrish Hosp, written consent, by random block division into 2 groups of 50 people (intervention and placebo group), DEX and placebo with shape, color, size and same packaging, A&B coding before use (not by researcher),10 minutes after induction until the end , intervention group under infusion of of DEX and placebo group under infusion of normal saline, recording information during and after operation by an experienced person (unfamiliar with the control & intervention groups), transfer to the recovery, observation and interview by trained personnel to evaluate variables (nausea,retching, vomiting, regurgitation), recording data in different minutes, making 2 files (intervention & control groups) for statistical use

Participants/Inclusion and exclusion criteria

Inclusion : Addicted ,age 20 - 60 , ASA 1& 2, SBP before & during operation between 90 - 140 mm Hg Exclusion : Laparotomy, surgery more than 4 hours, severe bleeding, ASA 3, motion sickness ,PONV, heart or GI disease, nausea & vomiting before surgery, drug withdrawal before surgery, anti-emetic drug use

Intervention groups

10 minutes after induction until the end, intervention group will undergo infusion of 1 microgram per minute DEX per kilogram of weight, placebo group will undergo N/S infusion

Main outcome variables

degrees of ponv (nausea,retcging,regurgitation ,vomiting) for intervention and control groups, main variable ponv, its degrees ,hemodynamic and demographic variables are secondary.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230728058951N1**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying effect of Dexmedetomidine on postoprative Nausea & Vomiting(PONV)In Laparascopic Cholecystectomy in Addict patient

Public title
Studying effect of Dexmedetomidine on postoprative Nausea & Vomiting(PONV)
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a history of addiction (according to definition) Age between 20 and 60 years ASA class one and two Blood pressure 24 hours before and during the operation between 140 and 90 mmHg
Exclusion criteria:
Intraoperative laparotomy Surgery lasting more than 4 hours Heavy bleeding ASA class three Any history of heart disease History of gastrointestinal disease Presence of nausea and vomiting before surgery Drug withdrawal symptoms before surgery Taking antiemetics History of motion sickness or PONV
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling is random, and the allocation is done according to the table of random numbers in two groups and the ratio of one to one in the intervention and control groups is done according to the sample size formula. Receiving dexmedetomidine or placebo are assigned based on the random number generation table. Patients are divided into two groups of 50 and each patient is randomly assigned a number. The control group includes numbers 1 to 50 and the intervention group includes numbers 51 to 100.
Blinding (investigator's opinion)
Double blinded
Blinding description
100 patients with drug addiction (according to the definition), candidates for laparoscopic cholecystectomy in Shohada Tajrish Hospital, who meet the entry criteria for the study, are informed by the trained personnel about the implementation and objectives of the study, and if they wish to participate in the study A written consent form is obtained from them and then each patient is classified according to the classification made using the random block division method and placed in the group receiving dexmethomidine (intervention group) or the placebo group (control group) means 2 groups of 50 people. It should be noted that if a patient is removed from the study for any reason, a person who has no knowledge of the intervention group and the control group will be randomly replaced with a new patient who meets the criteria for entering the project. With this process, the number of evaluated patients may exceed 100. Before the operation, each patient is interviewed by an anesthesiologist and demographic, hemodynamic, history and entry criteria are collected and the information is recorded in the relevant form. Dexmethomidine and placebo drugs are prepared with the same shape, color, size and packaging and are coded as A&B before injection by a person other than the researcher. The group under intervention with dexmethomidine drug 10 minutes after induction under dexmethomidine infusion 1 mcg/kg /min is placed and this continues until the end of the operation. And the placebo group also receives normal saline infusion 10 minutes after induction until the end of the procedure. The information is recorded from the time of arrival until 120 minutes later by the medical evaluator who does not know the type of patient group. After collecting all the information of the patients, this information will compiled into two files (the intervention group with dexmedetomidine and the control group with placebo) and will be used statistically.
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
13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran Street, between South Flamak St. and Zarafshan, Quds Town (West Town), Tehran
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Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.SBMU.MSP.REC.1402.105

Health conditions studied

1

Description of health condition studied

Effect of dexmedetomidine on postoperative nausea and vomiting (PONV)

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Post operative Nausea and vomiting (ponv) is one of the most unpleasant experiences that has important consequences on patient satisfaction, treatment results and related costs, and is one of the common causes of morbidity after surgery. Grades of (ponv) include nausea, retching, regurgitation or vomiting. ponv:It is one of the common causes of morbidity after surgery, which usually occurs during the recovery phase and ends spontaneously within 24 hours.it includes nausea that can end in retching or vomiting or regurgitation. Nausea:This is an unpleasant feeling that refers to the urge to vomit and is not accompanied by muscle movement outside the driver. Vomiting:It is the strong excretion of even small amounts of the contents of the upper GI tract through the mouth. Regurgitation:It is the exit of material from the pharynx or esophagus with low pressure, which is usually characterized by the presence of undigested food or blood. Retching:When even with muscular ejector efforts, no contents of the stomach are expelled through the mouth.

Timepoint

Measurement of presence Post operative nausea & vomitting and its levels in 15, 30, 45, 60, 90 and 120 minutes after the operation

Method of measurement

The interview includes asking the patient or the patient's complaint (in cases of nausea and regurgitation) and observation (in cases of vomiting and retching).

Secondary outcomes

1

Description

The secondary outcome variables are the degrees of postoperative nausea and vomiting including: nausea, regurgitation, retching, and vomiting, which were explained earlier.

Timepoint

Measuring the degree of postoperative nausea and vomiting in 15, 30, 45, 60, 90 and 120 minutes after the surgery.

Method of measurement

The interview includes asking the patient or the patient's complaint (in cases of nausea and regurgitation) and observation (in cases of vomiting and retching).

Intervention groups

1

Description

intervention group: The intervention group (including 50 people) will be subjected to intravenous infusion of dexmethomidine (an alpha 2 agonist drug) with dose of 1 mcg/kg/min, just from 10 minutes after induction of anesthesia until the end of the operation.

Category

Prevention

2

Description

Control group: The placebo group was given intravenous infusion of normal saline (0.9% saline), which is a physiological liquid,just from 10 minutes after induction of anesthesia until the end of the procedure.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

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1

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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
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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All the necessary information according to the regulations of the desired journal to print the article is available in the file sent to the journal office.

When the data will become available and for how long

Until the publication of the article

To whom data/document is available

all of people

Under which criteria data/document could be used

For public use, especially in the country's health sector

From where data/document is obtainable

Magazine office

What processes are involved for a request to access data/document

The desired and prescribed procedures of the journal office for publication and printing of articles

Comments

The useful point cannot be mentioned