Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effectiveness of two different doses of Dexmedetomidine on the prevention of nausea and vomiting in Discectomy under spinal anesthesia

Protocol summary

Study aim

Determination of the effect of two doses of dexmedetomidine on the prevention of nausea and vomiting in discectomy under spinal anesthesia

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 135 patients. Randomization was performed by individual block method using a table of random numbers.

Settings and conduct

This is a double-blind clinical trial that was performed on 135 patients undergoing spinal anesthesia Discectomy in Al-Zahra Hospital in Isfahan in 1398-99. After the approval of the university ethics committee and obtaining the patients' consent, the patients entered the groups by block random allocation. In each group, after spinal anesthesia, the desired intervention was applied and the patient's vital signs were measured and recorded. The clinical caregiver was different from the person injecting the drug and was unaware of the type of intervention being performed. The surgeon and the patient were also unaware of the intervention and were therefore blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 60 years old who are candidates for Discectomy under spinal anesthesia with ASA class 1 and 2. Exclusion criteria: history of cardiovascular disease, fever, obesity, pregnancy, Allergy to Dexmedetomidine , drug interaction with Dexmedetomidine

Intervention groups

Intervention group D1: 0.2 Micrograms per kilogram of body weight per hour of Dexmedetomidine brought to 10 cc by normal saline Intervention group D2: Dose of 0.5 Micrograms per kilogram of body weight per hour of Dexmedetomidine brought to 10 cc by normal saline Control group C: amount of 10 ml of normal saline, After spinal anesthesia and placing the patient in the desired position, it was received as an intravenous infusion pump for 10 minutes.

Main outcome variables

Nausea and vomiting due to dexmedetomidine injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N35**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **retrospective**

Last update: **2021-09-06, 1400/06/15**
Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

2019-06-30, 1398/04/09

Actual recruitment end date

2020-03-20, 1399/01/01

Trial completion date

2021-05-22, 1400/03/01

Scientific title

Comparison of the effectiveness of two different doses of Dexmedetomidine on the prevention of nausea and vomiting in Discectomy under spinal anesthesia

Public title

The effect of Dexmedetomidine on nausea and vomiting in Discectomy surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 to 60 years Candidate for Discectomy under spinal anesthesia Grade 1 and 2 Anesthesia Based on American Society Anesthesia Criteria

Exclusion criteria:

History of cardiovascular, respiratory, neurological, endocrine, thyroid, neuromuscular diseases, dysautonomia Fever Obesity (BMI> 27) History of vasoactive drugs, MAOI and TCA History of drug use Allergy to Pethidine, Ketamine and Magnesium sulfate Pregnancy Allergy to Dexmedetomidine Taking drugs with drug interactions with Dexmedetomidine

Age

From **18 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: **135**

Actual sample size reached: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a simple randomized clinical trial in which individuals enter study groups by lottery; The drugs and placebo are placed in the desired number in sealed opaque and uniform sealed envelopes. Each of the codes is also written on a piece of paper, folded and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box. Which is applied to the patient. This continues until the end of the paperwork so that the number of patients in the desired volume in the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This was a double-blind controlled clinical trial in which the patient and the evaluator had no known information about the type and dose of the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib St

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-07-24, 1400/05/02

Ethics committee reference number

IR.MUI.MED.REC.1398.173

Health conditions studied

1

Description of health condition studied

Nausea and vomiting due to Discectomy under spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nausea and vomiting due to dexmedetomidine injection

Timepoint

Immediately after spinal up to 24 hours after surgery

Method of measurement

Use Visual Analogue Scale or VAS

Secondary outcomes

1

Description

Heart Rate

Timepoint

Immediately after spinal up to 24 hours after surgery

Method of measurement

ECG monitoring

2

Description

Systolic blood pressure

Timepoint

Immediately after spinal up to 24 hours after surgery

Method of measurement

Barometer

3

Description

Diastolic blood pressure

Timepoint

Immediately after spinal up to 24 hours after surgery

Method of measurement

Barometer

4

Description

Arterial blood oxygen saturation

Timepoint

Immediately after spinal up to 24 hours after surgery

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group D1: From the time of entering the operating room until before spinal anesthesia, 500cc of Ringer's lactate serum made in Iran was administered intravenously to patients. After entering the operating room, before spinal anesthesia and dexmedetomidine injection, blood pressure (by non-invasive sphygmomanometer), arterial oxygen saturation (SpO2) were measured by pulse oximetry and baseline vital signs. Then 0.2 micrograms per kilogram of body weight per hour Dexmedetomidine made in Germany, which was increased to 10cc by normal saline, after spinal anesthesia and placing the patient in the desired position, was received as an intravenous infusion pump for 10 minutes. After that, the patient's vital signs were measured and recorded again until the end of surgery and then in recovery.

Category

Prevention

2

Description

Intervention group D2: From the time of entering the operating room until before spinal anesthesia, 500cc of Ringer's lactate serum made in Iran was administered intravenously to patients. After entering the operating room, before spinal anesthesia and dexmedetomidine injection, blood pressure (by non-invasive sphygmomanometer), arterial oxygen saturation (SpO2) were measured by pulse oximetry and baseline vital signs. Then 0.5 micrograms per kilogram of body weight per hour Dexmedetomidine made in Germany, which was increased to 10cc by normal saline, after spinal anesthesia and placing the patient in the desired position, was received as an intravenous infusion pump for 10 minutes. After that, the patient's vital signs were measured and recorded again until the end of surgery and then in recovery.

Category

Prevention

3

Description

Control group C: From the time of entering the operating room until before spinal anesthesia, 500cc of Ringer's lactate serum made in Iran was administered intravenously to patients. After entering the operating room, before spinal anesthesia, blood pressure (by non-invasive sphygmomanometer), arterial oxygen saturation (SpO2) were measured by pulse oximetry and baseline vital signs. Then, 10cc of normal saline made by Saha Med Company, after spinal anesthesia and placing the patient in the desired position, was received as an intravenous infusion pump for 10 minutes. After that, the patient's vital signs were measured and recorded again until the end of surgery and then in recovery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad Nazemoroaya

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Sponsors / Funding sources

1

Sponsor

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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
Esfahan 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
Esfahan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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