Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study and comparison of two different doses of propofol in prevention of nausea and vomiting in spinal discectomy

Protocol summary

Study aim
Comparison of two different doses of propofol in the prevention of nausea and vomiting in spinal discectomy

Design
This study is a clinical trial with a control group ,parallel group,double blind,randomized and sample size of 48 patients

Settings and conduct
This study is a double-blind clinical trial study (blinding method:physician & patient don't know which drug combination used). Performed in 1398-97 at AlZahraHospital in Isfahan,48patients were examined at the age of 18-65yo, candidates for discectomy surgery using spinal method.Patients'll be randomly divided into 3groups using SPSS software,1st group receiving low-dose propofol, 2nd group receiving the usual dose,and 3rd group (normal) saline. First, patients are given the necessary information,and written consent is obtained from each of them. Vital symptoms such as blood pressure, heart rate, o2sat drop, patient stay in recovery, and nausea and vomiting were recorded on the form. Patients' nausea and vomiting are checked until recovery.The implementation method is based on the modified Aldred score criterion. Severity of nausea is determined by VAS.If VAS<4, they'll be given 8mg / kg Ondansetron ampoule

Participants/Inclusion and exclusion criteria
Entry Criterion: 1-No reception of any sedative or narcotic drugs. 2-No gastrointestinal problems 3-age between 18 and 65 years old. 4-Having an informed consent Exclude Criteria: 1- any change in the relaxation method and surgical method 2-patient's age is more than 65y or less than18y

Intervention groups
In 3 groups (2 case groups,1control group),effect of different dosage of Propofol on the prevention of nausea and vomiting after some surgeries

Main outcome variables
Patient's age & sex, group of patients,vomiting,BP,O2sat, HR, recovery time, receiving 8mg/kg ondansetron,propofol dosage, nidel location, severity of nausea, duration of action, duration of anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N21**
Registration date: **2020-06-29, 1399/04/09**
Registration timing: **retrospective**

Last update: **2020-06-29, 1399/04/09**
Update count: **0**

Registration date
2020-06-29, 1399/04/09

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3212 3543

Email address
behzad_nazem@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2018-03-21, 1397/01/01

Actual recruitment end date
2019-03-21, 1398/01/01
Trial completion date
2020-03-19, 1398/12/29

Scientific title
Study and comparison of two different doses of propofol in prevention of nausea and vomiting in spinal discectomy

Public title
Study of effectiveness of propofol dosage in prevention of nausa and vomiting in some surgeris
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The person should not have received any sedative or narcotic drugs No gastrointestinal problems such as reflux Patients should be between 18 and 65 years old. Having a informed consent to enter the research
Exclusion criteria:
If there is any change in the relaxation method and the change in the surgical method, the patient should be excluded from the study. The patient's age is more than 65 years The patient's age is less than 18 years
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **48**
Actual sample size reached: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
After sampling and selecting the list of patients, using spss software, edit 18, the order of patients entering the 3 groups under study is determined completely randomly based on the order in the random list of spss.
Blinding (investigator's opinion)
Double blinded
Blinding description
The doctor and the patient do not know the type of drug combination used
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjrib Street, Daneshgah Blvd,
City
isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-05-24, 1398/03/03
Ethics committee reference number
IR.MUI.MED.REC.1398.083

Health conditions studied

1

Description of health condition studied
Nausea
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Vomit
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nausea score based on VAS criteria
Timepoint
During recovery time after surgery
Method of measurement
questionnaire

2

Description
To vomit or not to vomit
Timepoint
During recovery time after surgery
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: First, patients are given the necessary information about the type of operation and sedation method, and written consent is obtained from each of them. Vital symptoms such as blood pressure, heart rate, o2sat drop, patient stay in recovery, and nausea and vomiting were recorded on the form. Then a low-dose propofol (0.1 mg / Kg) is prescribed for group 1, and patients' nausea and vomiting are checked until recovery. The implementation method is based on the modified Aldred score criterion.

Category
Treatment - Drugs

2

Description
Intervention group 2: First, patients are given the necessary information about the type of operation and sedation method, and written consent is obtained from each of them. Vital symptoms such as blood pressure, heart rate, o2sat drop, patient stay in recovery, and nausea and vomiting were recorded on the form. The usual dose of propofol (0.25 mg / Kg) is then prescribed for group 2 and the patient's nausea and vomiting are checked until recovery. The implementation method is based on the modified Aldred score criterion.

Category
Treatment - Drugs

3

Description
Control group: First, patients are given the necessary information about the type of procedure and sedation method, and written consent is obtained from each of them. Vital signs such as blood pressure, heart rate, o2sat drop, patient stay in recovery, and nausea and vomiting were recorded on the form. Normal saline (0.25 mg / kg) is then administered and the patient's nausea and vomiting are checked until recovery. The implementation method is based on the modified Aldred score criterion.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahara hospital

Full name of responsible person
Behzad Nazemroaya

Street address
Soffeh boulivard, Shahid Keshvari highway

City
isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
behzad_nazem@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
shaghayegh haghjoo

Street address
Hezar Jarib Street

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0048

Email
research@mui.ac.ir

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

Full name of responsible person
Samin Mohammadi

Position
medical student / intern

Latest degree
Medical doctor

Other areas of specialty/work

General Practitioner

Street address
Tohid Street

City
Isfahan

Province
Isfehan

Postal code
۸۱۷۳۹۳۳۷۵۲

Phone
+98 31 3624 8494

Email
saminmhmd@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Behzad Nazemroaya

Position
Assistant Professor/Faculty

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology, AL-Zahra Hospital

City
Isfahan

Province
Isfehan

Postal code
8146713543

Phone
0098316202020

Email
behzad_nazem@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Samin Mohammadi

Position
medical student / intern

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Tohid Street

City
Isfahan

Province
Isfehan

Postal code
۸۱۷۳۹۳۳۷۵۲

Phone
+98 31 3624 8494

Email
saminmhmd@gmail.com

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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available