

# 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 nausea and vomiting in some surgeries

**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 an 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**

Isfahan

**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 boulevard, Shahid Keshvari highway

##### City

isfahan

##### Province

Isfahan

##### 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

Isfahan

##### 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**

Isfahan

**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**

Isfahan

**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**

Isfahan

**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