

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of the effect of isometric exercise and lidocaine 2% on pain relief during propofol intravenous injection

#### Protocol summary

##### Study aim

Determination of the effect of isometric exercise and lidocaine 2% in reducing pain during propofol injection

##### Design

Clinical trial with control group, with parallel groups, blind, randomized

##### Settings and conduct

This is a randomized clinical trial. The study population consisted of 120 patients aged 20-60 years who are candidates for various surgeries at 22 Bahman Neishabour Hospital. Four- Point pain scale is used to evaluate pain. painless (0), low pain sensation (1), moderate pain (2), severe pain and with or without movement of the limbs and facial muscles (3 ). Patients are divided into groups A, B, and C, based on random allocation by random numbers table: In group C, each isometric exercise cycle consists of 3s of exercise and t3s of rest. In this study, the participants and the person evaluating pain intensity are blinded to the method of work.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for general anesthetic surgery ages of 20-60 consent and willingness to participate in the research ASA I, II Not sensitive to the drugs studied Having at least a fifth grade of elementary school Ability to communicate with the research team No addiction Exit criteria: Having Nervous-Muscular Diseases, heart disease ,history of seizures Having metabolic and gastrointestinal disorders Severe nervous and psychiatric disorders Sedation and narcotics Alcoholic patients Sedative or analgesic Need for induction of anesthesia and rapid intubation ESRD Liver disorders

##### Intervention groups

Group A: Propofol injections of 1% pure (control) Group B: injection of propofol with 40 mg lidocaine 2% (intervention) Group C: Perform 5 isometric exercise cycles and then administer 1% pure propofol (intervention).

#### Main outcome variables

Intensity of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190109042309N1**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **prospective**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

##### Registration date

2019-02-06, 1397/11/17

##### Registrant information

##### Name

Zohreh Mohamadzadeh Tabrizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4401 8329

##### Email address

mohammadzadehz@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-06-21, 1398/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of isometric exercise and lidocaine 2% on pain relief during propofol intravenous injection

**Public title**

effect of isometric exercise on pain relief during propofol intravenous injection

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient is a candidate for general anesthetic and surgery The patient is between the ages of 20 and 60 The patient has the consent and willingness to participate in the research American Society of Anesthesiology Class I, II Having at least a fifth grade of elementary school Ability to communicate with the research team

**Exclusion criteria:**

Not sensitive to the drugs studied No addiction Having Nervous-Muscular Diseases Having heart disease and history of seizures Having metabolic and gastrointestinal disorders Severe nervous and psychiatric disorders Class 3 and 4 American Anesthesiology Society Need for induction of anesthesia and rapid intubation Kidney disease in the final stage Liver disorders

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A person randomly assigns to one of the three study groups with using random number table and receive the intervention of the same group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants and the person evaluating the outcome are blind

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

**Street address**

Deputy Director of Research and Technology, University of Medical Sciences , Sabzevar

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9717913112-971791311

**Approval date**

2018-12-29, 1397/10/08

**Ethics committee reference number**

IR.MEDSAB.REC.1397.088

**Health conditions studied****1****Description of health condition studied**

Pain caused by injection of propofol

**ICD-10 code**

R52.9

**ICD-10 code description**

XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

**Primary outcomes****1****Description**

Intensity of pain

**Timepoint**

At the time of induction of anesthesia

**Method of measurement**

Assessment of Pain Scores of 4-point Verbal Rating Scale (VRS) during Injection of Propofol

**Secondary outcomes**

empty

**Intervention groups****1****Description**

1. Intervention group: Perform isometric exercise before propofol injection

**Category**

Prevention

## 2

### Description

2. Intervention group: Lidocaine injection 2% before propofol injection

### Category

Prevention

## 3

### Description

Control group: Propofol injection

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

22 Bahman Hospital in Neyshabour

##### Full name of responsible person

Mahdieh Anjidani

##### Street address

22 Bahman Hospital, Ave Emam, Neyshabour Town

##### City

Neyshabour

##### Province

Razavi Khorasan

##### Postal code

93186-14139

##### Phone

+98 51 4441 8369

##### Email

Razaviamir78@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Zohreh Mohamadzadeh Tabrizi

##### Street address

Sabzevar University of Medical Sciences, Sabzevar

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Sabzevar

##### Province

Razavi Khorasan

##### Postal code

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##### Phone

+98 51 4401 8329

##### Email

mohamadzadehtz1@gmail.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

##### Full name of responsible person

Zohreh Mohamadzadeh Tabrizi

##### Position

Lecturer

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Faculty of Paramedicine, Sabzevar University of Medical Sciences, Sabzevar

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+98 51 4401 8329

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##### Email

mohammadzadehz@medsab.ac.ir

## Person responsible for scientific inquiries

#### Contact

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Sabzevar University of Medical Sciences

##### Full name of responsible person

Zohreh Mohamadzadeh Tabrizi

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

The results of the research are published

**When the data will become available and for how long**

Starting available 6 months after the publication of results

**To whom data/document is available**

Internal Scientists at Sabzevar University of Medical Sciences

**Under which criteria data/document could be used**

Just for reading

**From where data/document is obtainable**

Email address

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

Email address

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Zohreh Mohamadzadeh Tabrizi

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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