Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 51 4401 8329

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
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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
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Other areas of specialty/work
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Person responsible for updating data

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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