

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of three methods of Valsalva maneuver, Lidocaine, and Valsalva maneuvers along with administration of Lidocaine to reduce the pain associated with administration of Propofol

Protocol summary

Study aim

To compare Valsalva maneuver, Lidocaine, and Valsalva maneuvers along with administration of Lidocaine to reduce the pain associated with administration of Propofol in Alzahra hospital in 2020

Design

Open label randomized clinical trial, with three parallel groups, randomized with block randomization, phase 3, on 111 patients overall.

Settings and conduct

The study is a clinical trial, in which cases are divided into 3 groups by block randomization: 1. Valsalva maneuver, 2. lidocaine, and 3. Valsalva maneuver along with prescription of lidocaine. It will be carried out in October 2020, in Alzahra hospital, Isfahan, Iran. After informed consent, Candidates for sedation with propofol are divided in 3 groups and their demographic information and VAS scores are recorded. Only data analyst is blinded in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Physical class I or II 2. Age between 18 to 65 years old 3. Propofol administration as sedative. Exclusion criteria: 1. History of mental, cardiac and respiratory disease 2. Chronic pain disorders 3. Long history of analgesic use 4. History of allergic reactions propofol or lidocaine 5. History of drug abuse

Intervention groups

Group 1- Performing Valsalva maneuver by the patient; 2- Lidocaine injection; and 3- Lidocaine injection while the patient is performing Valsalva maneuver. Lidocaine dose is 1 mg/Kg of body patient's weight slow bolus intravenous (over 2-3 min)

Main outcome variables

Visual Analog Scale (VAS) for pain Objective physician-assessed pain score; with: 0= no pain; 1= mild pain, pain that only is reported by the patient, and no signs of pain are observed by the physician; 2= Moderate pain, one

pain sign is observed in addition to patient's report 3= Severe pain with loud noise or moaning.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N27**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **prospective**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-24, 1399/09/04

Expected recruitment end date

2020-12-13, 1399/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three methods of Valsalva maneuver, Lidocaine, and Valsalva maneuvers along with administration of Lidocaine to reduce the pain associated with administration of Propofol

Public title

The effect of Valsalva maneuver, Lidocaine and Valsalva maneuver and Lidocaine injection on reducing the pain of Propofol injection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for general anesthesia Physical condition in ASA class I and II Age 18 to 65 years old Able to perform Valsalva maneuver

Exclusion criteria:

History of mental, cardiac and respiratory diseases Chronic pain disorders Long history of analgesic use History of allergies to propofol and Lidocaine History of drug abuse

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is used in this study to divide cases in 3 groups. SAS algorithm was used to perform blocked randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Isfahan University of Medical Sciences Committee for Ethics in Biomedical Research

Street address

Isfahan University of Medical Sciences, Hezar Jerib street

City

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Province

Isfahan

Postal code

8174673461

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.MUI.MED.REC.1399.658

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

Local injection site pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

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

Local propofol injection site pain measured by visual analog scale

Timepoint

Right after propofol injection

Method of measurement

visual analog scale / Objective physician-assessed pain score; with: 0= no pain;1= mild pain, pain that only is reported by the patient, and no signs of pain are observed by the physician;2= Moderate pain, one pain sign is observed in addition to patient's report3= Severe pain with loud noise or moaning

Secondary outcomes

empty

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

Intervention group: The patient is asked to perform Valsalva maneuver at the time of propofol injection.

Category

Prevention

2**Description**

Intervention group: Intravenous Lidocaine bolus injection

of 1mg/Kg of body weight, over 2-3 minutes

Category

Prevention

3**Description**

Intervention group: The patient is asked to perform Valsalva maneuver at the time of propofol injection. In the meantime intravenous Lidocaine bolus dose of 1mg/Kg of body weight, is injected over 2-3 minutes.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Behzad Nazem roaya

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Vice Chancellor for Research, Isfahan 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

Behzad Nazem roaya

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

There is a possibility that our subjects would not be willing to consent to their data being shared.

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable