Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effectiveness of tourniquet ligation and Valsalva maneuver in relieving pain caused by Propofol injection to induce general anesthesia

Protocol summary

Study aim
Comparison of the effect of Valsalva maneuver and tourniquet closure on propofol injection pain

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 105 patients. Random allocation software random numbers are used for randomization.

Settings and conduct
This study is a double-blind clinical trial that will be performed on 105 patients undergoing surgery under general anesthesia at Al-Zahra Hospital in Isfahan.After reviewing the inclusion criteria, patients will be informed about the study and if they are satisfied, the relevant intervention will be applied to them.After lying on the operating table and connecting the monitor and then closing the tourniquet and the Valsalva maneuver, the amount of pain caused by the injection of Propofol will be measured and the results will be recorded and evaluated. The clinical caregiver as well as the person injecting the drug are different from the person performing the intervention and are unaware of the intervention. Therefore, the patient is unaware of the type of intervention performed and is blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years, Candidate for surgery under propofol anesthesia, ASA I and ASA II anesthesia class, able to perform Valsalva maneuver Exclusion criteria: having respiratory problems, drug and stimulant addiction, propofol allergy, underlying disease, taking any analgesic and anesthetic prophylaxis

Intervention groups
Intervention group A: Valsalva maneuver is performed in real time and the tourniquet is closed schematically before Propofol injection. Intervention group B: Closing the tourniquet in real time and maneuvering Valsalva schematically before injecting Propofol. Control group C: Valsalva maneuver and tourniquet closure applied schematically before Propofol injection.

Main outcome variables
Pain from Propofol injection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N28**
Registration date: **2020-12-09, 1399/09/19**
Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**
Update count: **0**

Registration date
2020-12-09, 1399/09/19

Registrant information

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Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of tourniquet ligation and Valsalva maneuver in relieving pain caused by Propofol injection to induce general anesthesia

Public title
The effect of Valsalva maneuver and tourniquet closure on Propofol injection pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years ASA class I and II candidate for surgery under the general anesthesia Able to perform Valsalva maneuver
Exclusion criteria:
Having respiratory problems Drug addiction and stimulants Allergy to Propofol Having underlying diseases such as diabetes, cardiovascular problems, liver disorders Existence of chronic pain syndromes and thrombophlebitis Take any analgesic and sedative before anesthesia
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by block method; As the number of patients in all three groups is the same, each patient is assigned a code using a random number table (Random allocation software) and patients enter one of the groups according to these codes.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind study in which the clinical caregiver and the person injecting the drug are different from the person performing the intervention and are unaware of the intervention.Patients in each group are also told that in order to reduce the pain of injecting two Valsalva maneuvers and closing the tourniquet, they are also told that depending on their group, only one of these interventions can be real and may even The two interventions are not real to determine the effect of the intervention. Therefore, patients are not aware of the type of intervention and are kept blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences Committe for Ethics in Biomedical Research
Street address
Hezar Jarib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-10-16, 1399/07/25
Ethics committee reference number
IR.MUI.MED.REC.1399.638

Health conditions studied

1

Description of health condition studied
Pain from propofol injection
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Pain from propofol injection
Timepoint
20 seconds after propofol injection
Method of measurement
withdrawal response score questionnaire

Secondary outcomes

1

Description
Blood Pressure
Timepoint
Before intervention, after intervention, after injection of propofol every 1 to 3 minutes, 5 minutes after induction of anesthesia, 10 minutes after induction of anesthesia
Method of measurement
Barometer

2

Description
Heart Rate
Timepoint
Before intervention, after intervention, after injection of propofol every 1 to 3 minutes, 5 minutes after induction of anesthesia, 10 minutes after induction of anesthesia
Method of measurement
ECG monitoring

3

Description
Arterial blood oxygen saturation
Timepoint
Before intervention, after intervention, after injection of propofol every 1 to 3 minutes, 5 minutes after induction of anesthesia, 10 minutes after induction of anesthesia
Method of measurement
Pulse Oximeter

Intervention groups

1

Description
Intervention group A: Patients first receive 2 ml of normal saline intravenously and after 3 minutes while the tourniquet is closed schematically, they perform the Valsalva maneuver by blowing in a plastic tube for at least 20 seconds. Propofol injection begins at the end of the Valsalva maneuver.
Category
Prevention

2

Description
Intervention group B: First the tourniquet is closed and then 2 ml of normal saline is given intravenously and then 30 seconds later, while there is a plastic tube for schematic of Valsalva maneuver, intravenous propofol is injected and then the tourniquet is released.
Category
Prevention

3

Description
Control group C: There is both a tourniquet and a plastic tube, but the intervention is performed schematically and patients receive 2 ml of normal saline intravenously and then intravenous propofol injection is started.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available