Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the effect of lidocaine and cold normal saline on pain during propofol injection

Protocol summary

Study aim
Comparison of the effect of lidocaine and cold saline on reducing the pain of propofol injection

Design
A double-blind clinical trial with randomized groups with SPSS software is performed in phase 3 with a control group with a sample size of 120 people.

Settings and conduct
Ayatollah Rouhani Educational and Medical Center in Babol In this study, both patients and researchers who recorded the severity of propofol injection pain were blinded.

Participants/Inclusion and exclusion criteria
Candidate patients for general anesthesia with propofol selected / entry criteria is patients of 18 to 60 years old with ASA class one and two and no entry with underlying heart disease, history of seizures, lidocaine sensitivity.

Intervention groups
Three groups of patients are candidates for general anesthesia receiving lidocaine, normal saline at 4 ° C and normal saline at room temperature.

Main outcome variables
Changes in amount of pain at the injection site of propofol.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141121020020N7**
Registration date: **2021-06-08, 1400/03/18**
Registration timing: **retrospective**

Last update: **2021-06-08, 1400/03/18**
Update count: **0**

Registration date
2021-06-08, 1400/03/18

Registrant information

Name
Shahram Seyfi

Name of organization / entity
Babol University of Medical Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-13, 1399/12/23

Expected recruitment end date
2021-05-13, 1400/02/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of lidocaine and cold normal saline on pain during propofol injection

Public title
The effect of lidocaine and cold normal saline on injection pain

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Indication of propofol injection Elective general anesthesia

Exclusion criteria:
Known heart disease History of lidocaine sensitivity

Patient dissatisfaction History of seizures History of psychiatric illness

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by random blocks with block size of 6 and number of blocks of 20. First, twenty random blocks of AABBCC letter permutations are generated by the randomization site and recorded in one sheet, respectively, and then the patients will be assigned to one of the three study groups according to the permutations generated. The website address is WWW.RANDOMIZATION.COM. The tab generated by the randomization site is a tab similar to the following table: 1.A 2.B 3.B 4.C 5.A 6.C . . . 120.C Then, each patient who is admitted is assigned to one of the groups according to the above sheet and the patient's entry and the desired number, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is generally explained to patients that they will receive one of the three drugs of study and patients fill and sign an informed consent form. Patients who are candidates for this study are divided into three groups of 40 for lidocaine injection, cold normal saline at 4 ° C, and normal saline at room temperature as the control group. The drugs are prepared in exactly the same packaging in terms of shape and size in 10 cc syringes with a unique 4-digit code. All drugs are injected by a trained anesthetist. After injecting the drugs, the anesthesiologist leaves the room without giving further information to the researcher. In the informed consent form, the whole study process and the studied drugs are explained to the patient, but the patients are not aware of the drug they are receiving.

Placebo

Used

Assignment

Parallel

Other design features

Patients are randomly assigned to study groups by permutation block method. Medication is assigned by a nurse.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Ganj Afrouz St.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2020-08-31, 1399/06/10

Ethics committee reference number

IR.MUBABOL.REC.1399.426

Health conditions studied

1

Description of health condition studied

Pain at the injection site

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain severity at the injection site

Timepoint

At beginning, at 15 and 30 seconds after injection

Method of measurement

Questionnaire and VAS scoring scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lidocaine receiving group. Patients in this group receive 10 ml of 0.5% lidocaine as an intervention group.

Category

Prevention

2

Description

Intervention group: Recipient of normal saline 4 ° C. Patients in this group receive 10 ml of normal cold saline 4 ° C as an intervention group.

Category
Prevention

3

Description
Control group: Normal saline recipient with ambient temperature. Patients in this group receive 10 ml of normal saline at room temperature as a control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayattolah Rohani Hospital
Full name of responsible person
Shahram Seyfi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Deputy of research and Technology of Babol university of medical sciences
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Ganj afrouz st. Babol University of Medical Sciences
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Shahram Seyfi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Raw and analyzed information obtained from all stages of the study

When the data will become available and for how long

unlimited

To whom data/document is available

All researchers with professional and ethical competence in the field of clinical affairs

Under which criteria data/document could be used

Provided there is no conflict of interest between the researchers, the responsible institution and the patients

From where data/document is obtainable

Vice Chancellor for Research, Babol University of Medical Sciences mubabol.ac.ir

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

This study will be conducted according to the administrative procedure of the licensing institution.

Comments