

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3223 8284

##### Email address

sh.seyfi@mubabol.ac.ir

#### 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 AABCC 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

**Street address**

Ganj afrouz st.

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Mazandaran

**Postal code**

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**Phone**

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**Email**

rohani@mubabol.ac.ir

**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

**Street address**

Ganj afrouz st. Babol University of Medical Sciences

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**Email**

info@mubabol.ac.ir

**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**

Anesthesiology

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

Babol University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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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**