

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of the effect of Dexmedetomidine with intravenous Paracetamol on Pain induced by Propofol 40c injection; A double-Blind Randomized Clinical Trial

#### Protocol summary

##### Study aim

Comparison of the effect of dexmedetomidine with intravenous paracetamol on Propofol injection pain

##### Design

Double-Blind Randomized Clinical Trial, Phase 3 on 90 patients, Web-based randomization software was used for randomization.

##### Settings and conduct

The present study will be conducted in the context of reducing Propofol injection pain in 90 patients aged 18-60 years who are candidates for surgery under general anesthesia at Imam Ali Hospital, North Khorasan University of Medical Sciences. Patients are divided into three groups in a blocked random allocation using the web-based system. Pain assessment will be done by a visual analog scale and Numeric rating scale measurement tool about 5 to 10 seconds after the injection of the targeted dose of Propofol. To perform blinding, the patients, the surgeon, and the person performing the evaluation at different intervals will be blinded to the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients must be alert. Be candidate for surgery under general anesthesia. Do not have heart diseases. Has not taken painkillers In 24 hours before surgery. Exclusion criteria: Do not be allergic to the drugs in the study.

##### Intervention groups

In the first group of patients, they receive Dexmedetomidine (0.5 µg/kg) slowly over a period of 5 minutes. In the second group of patients, Paracetamol (at the rate of 2 mg/kg) is slowly received over a period of 5 minutes. In the third group of patients, they receive Lidocaine (40 mg diluted in 10 cc of water) slowly over a period of 3 minutes. All injection will be done through a tee connector.

##### Main outcome variables

Pain during Propofol injection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141001019359N14**

Registration date: **2022-09-28, 1401/07/06**

Registration timing: **prospective**

Last update: **2022-09-28, 1401/07/06**

Update count: **0**

##### Registration date

2022-09-28, 1401/07/06

##### Registrant information

##### Name

Hossein Zeraati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3151 0000

##### Email address

zeraatih911@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-07, 1401/07/15

##### Expected recruitment end date

2023-02-04, 1401/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of Dexmedetomidine with intravenous Paracetamol on Pain induced by Propofol 40c injection; A double-Blind Randomized Clinical Trial

**Public title**

Comparison of the effect of Dexmedetomidine with intravenous Paracetamol on Pain induced by Propofol

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient must be alert The patient must be a candidate for surgery under general anesthesia The patient must not have coagulation problems The patient must not be allergic to Propofol or the other drugs in the study The patient must not have cardiovascular problems

**Exclusion criteria:**

Patients who are addictive or have drug abuse Patients with hepatic failure

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling in this study will be that first in order to enter the study patients will be in the form of non-random sampling of the type "available" and then divide them into three groups by randomly assigned blocking using a web-based system. Random blocking at [www.randomization.com](http://www.randomization.com) will be done in 15 blocks of 6. So that in each block, there are 2 people in the first group (A), two people in the second group (B) and two people in the third group (C). After a random sequence was identified in all blocks, cards were written by writing C, B, and A to indicate which group each patient was assigned to, and by someone other than the research team from 1 to 90 in all blocks, respectively. They are numbered and these cards are placed in sealed non-transparent envelopes, respectively. Then, in order to hide the random allocation, when the patient visits, the opaque sealed envelope will be opened and then one by one, it will be determined for each sample of the relevant group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

None of the participants in the study will be aware of the randomization list, and in order to conceal the randomization process, the groups will be placed in closed envelopes in the reception area and will be assigned to the eligible individuals who enter the study. Also, in order to blind the patients to the study groups, all patients will receive the desired drugs intravenously and In order to blind the anesthetist nurse (who is responsible for injecting drugs intravenously for patients), the arms of all patients will be covered with a cloth.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

**Street address**

Vice Chancellor for Research of North Khorasan University of Medical Sciences, Bojnurd

**City**

Bojnord

**Province**

North Khorasan

**Postal code**

9416678894

**Approval date**

2022-09-04, 1401/06/13

**Ethics committee reference number**

IR.NKUMS.REC.1401.041

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

Pain

**ICD-10 code**

R52.0

**ICD-10 code description**

Pain, not elsewhere classified

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

Propofol injection pain

**Timepoint**

Measuring pain in a time interval of 5 to 10 seconds during Propofol injection

**Method of measurement**

Visual Analog Score (VAS) Form of pain and Numeric rating scale (NRS) For rating the pain

**Secondary outcomes**

**1**

**Description**

Mean Arterial Pressure (MAP)

**Timepoint**

Before Propofol injection, 5 seconds after Propofol injection, 30 seconds after Propofol injection

**Method of measurement**

Use of Monitoring device

**2**

**Description**

Heart Rate (HR)

**Timepoint**

Before Propofol injection, 5 seconds after Propofol injection, 30 seconds after Propofol injection

**Method of measurement**

Use of monitoring device

**3**

**Description**

Length of recovery and return from anesthesia

**Timepoint**

From extubation until the patient regains consciousness

**Method of measurement**

Time observation

**Intervention groups**

**1**

**Description**

Intervention group A: Before induction of anesthesia, Dexmedetomidine (0.5 µg/kg) will be slowly injected for 5 minutes.

**Category**

Prevention

**2**

**Description**

Intervention group B: Before induction of anesthesia, Paracetamol (2 mg/kg) will be slowly injected for 5 minutes.

**Category**

Prevention

**3**

**Description**

Control group: Before induction of anesthesia 40 mg of Lidocaine is dissolved in a 10 cc syringe and will be

slowly injected to the patient over a period of 3 minutes.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Ali hospital

**Full name of responsible person**

Ali Esmaeili

**Street address**

Emam Ali hospital, Bojnurd, Iran

**City**

Bojnurd

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North Khorasan

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9416678894

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+98 58 3229 7010

**Email**

dresmaely8@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Amirali Ghahramani

**Street address**

Vice Chancellor for Research, North Khorasan University of Medical Sciences, Shahriar St. Bojnurd, North Khorasan, Iran

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iran6289@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Bojnourd 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

North Khorasan

**Postal code**

9416678894

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+98583151

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dresmaely8@gmail.com

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

Bojnourd University of Medical Sciences

**Full name of responsible person**

Ali Esmaeili

**Position**

Faculty Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

Faculty Anesthesiologist

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Specialist

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

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**Position**

Faculty Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

North Khorasan School of Medicine, Bojnurd, iran

**City**

Bojnurd

**Province****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 no further information.

**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**

No - There is not 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