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 4oc 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 4oc 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 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

Province

North Khorasan

Postal code

9416678894

Phone

+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

City

Bojnurd

Province

North Khorasan

Postal code

9416678894

Phone

+98 58 3151 1421

Email

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

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
Street address
North Khorasan School of Medicine, Bojnurd, iran
City
Bojnurd
Province
North Khorasan
Postal code
9416678894
Phone
+98583151
Email
dresmaely8@gmail.com

Person responsible for scientific 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
Street address
North Khorasan School of Medicine, Bojnurd, iran
City
Bojnurd
Province
North Khorasan
Postal code
9416678894
Phone
+98583151
Email
dresmaely8@gmail.com

Person responsible for updating data

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
Street address
North Khorasan School of Medicine, Bojnurd, iran
City
Bojnurd
Province
North Khorasan
Postal code
9416678894
Phone
+98583151
Email
dresmaely8@gmail.com

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