

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Intrathecal addition of Dexmedetomidine and Sufentanil to Bupivacaine in Patients Undergoing Knee Prosthesis under Spinal Anesthesia: a Double-blind Randomized Clinical Trial

Protocol summary

Study aim

Comparison of the effect of intrathecal addition of dexmedetomidine and sufentanil to bupivacaine in patients undergoing knee prosthesis by spinal anesthesia

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 is a double-blind clinical trial that will be performed on patients aged 40 to 70 years referred to Imam Ali (AS) Teaching Hospital in Bojnourd. Patients are randomly assigned to three groups (two interventions and control) blocked by a web-based system. The level and duration of analgesia will be assessed by a measuring instrument. To perform blinding, patients and the person performing the pain assessment work at different intervals will be blinded to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients be vigilant. Do not Have history of previous surgery. Do not Have history of taking anti-anxiety, analgesic and sedative drugs. Do not Have history of allergies to drugs used in the study. Patients should be between 40 and 70 years old. Exclusion criteria: Patients undergoing general anesthesia for any reason after spinal anesthesia.

Intervention groups

In the first group, patients in combination with the main drug (bupivacaine); They will receive 10 micrograms of intrathecal dexmedetomidine. In the second group, patients in combination with the main drug (bupivacaine); will receive micrograms of intrathecal sufentanil. In the third group, patients will receive only bupivacaine.

Main outcome variables

Level and duration of analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141001019359N12**

Registration date: **2022-04-08, 1401/01/19**

Registration timing: **prospective**

Last update: **2022-04-08, 1401/01/19**

Update count: **0**

Registration date

2022-04-08, 1401/01/19

Registrant information

Name

Hossein Zeraati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Intrathecal addition of Dexmedetomidine and Sufentanil to Bupivacaine in Patients Undergoing Knee Prosthesis under Spinal Anesthesia: a Double-blind Randomized Clinical Trial

Public title

Comparison of the effect of Intrathecal addition of Dexmedetomidine and Sufentanil to Bupivacaine in Patients Undergoing Knee Prosthesis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be vigilant Do not Have history of previous surgery, Do not Have history of taking anti-anxiety, analgesic and sedative drugs Do not Have history of allergies to drugs used in the study Do not have drug addiction. Age between 40 to 70 years

Exclusion criteria:

Patients undergoing general anesthesia for any reason after spinal anesthesia

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- 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 intervention 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. Participants also referred to the type of intervention (drugs in the syringe for injection into the intrathecal space) because the syringes had already been diluted to the same volume; And the position of the patients will not be known during the spinal anesthesia technique. Therefore, the study is double-blind so that patients and the outcome assessment specialist are unaware of the status of the three groups assigned to the study.

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

Bojnurd

Province

North Khorasan

Postal code

9416678894

Approval date

2022-02-27, 1400/12/08

Ethics committee reference number

IR.NKUMS.REC.1400.159

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Level of analgesia

Timepoint

After performing spinal anesthesia technique

Method of measurement

Pin Prick method

2

Description

duration of analgesia

Timepoint

The patient's first request for an analgesic injection

Method of measurement

Researcher-made questionnaire

3

Description

Intensity of pain

Timepoint

The patient's first request for an analgesic injection

Method of measurement

visual analog scale

Secondary outcomes

1

Description

Physiological parameters (blood pressure, heart rate, mean arterial pressure)

Timepoint

After the spinal technique, for the first 15 minutes every 2 minutes and then every 4 minutes until the end of surgery

Method of measurement

Cardiac monitoring

2

Description

Drug side effects

Timepoint

End of surgery up to 24 hours later

Method of measurement

Researcher-made questionnaire

Intervention groups

1

Description

Intervention group 1: In this group of patients to perform spinal anesthesia, anesthesiologist in combination with the main anesthetic drug (bupivacaine); 10 micrograms of dexmedetomidine will be injected into the intrathecal space.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group of patients to perform spinal anesthesia, anesthesiologist in combination with

the main anesthetic drug (bupivacaine); 0 micrograms of sufentanil will be injected into the intrathecal space.

Category

Treatment - Drugs

3

Description

Control group: In this group of patients, for spinal anesthesia, the anesthesiologist will inject only the main anesthetic (bupivacaine) into the intrathecal space.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Hospital

Full name of responsible person

Javad Shahinfar

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Emam Ali Hospital, Bojnurd, Iran.

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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?

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

School of Nursing and Midwifery, Shahriyar Ave,
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Person responsible for general inquiries

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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

اطلاعات بیشتری وجود ندارد.

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