Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparative study of the effect of two continuous epidural methods and continuous paravertebral block on pain after knee arthroplasty surgery

Protocol summary

Study aim

compare the role of continuous epidural method and continuous paravertebral in analgesia after knee arthroplasty

Design

Patients were randomly divided into two groups (n = 19) continuous epidural and continuous paravertebral block.Patients were completely randomly divided into four groups of continuous epidural receiving and continuous paravertebral block by Blocked Randomization method. Using the table of random numbers and quadratic blocks, the following conditions were obtained in which group A individuals received continuous epidural and group B individuals received continuous paravertebral block. Putting four blocks together creates situations that are completely random and randomly divided patients)In order to blind and hide the samples, a special code is written for each patient in a sealed envelope, which is opened only before attempting to anesthetize the patient and only by the researcher and in complete secrecy, and informs the patient group

Settings and conduct

Recovery of the general operating room of Rasoul Hospital. In both groups, 15 mg bupivacaine injection of 0.25% was performed in L2 / 3 space and epidural and paravertebral catheters were implanted in the respective groups and finally the pain pump was connected to the catheter.To blind and hide the samples For each patient, a special code is written inside the sealed envelope, which was opened only before the patient was anesthetized

Participants/Inclusion and exclusion criteria

Admission: Physical level one and two. age 40 to 70 years. Satisfaction with the study No entry: Allergy to any of the drugs used in the study. body mass index>40. severe liver and heart disease. addiction or prolonged use of analgesia

Intervention groups

the effectiveness of Continuous paravertebral block performed to reduce pain after knee surgery.

Main outcome variables

Pain intensity in static and dynamic posture؛mobility؛muscle strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191013045095N1**
Registration date: **2021-09-10, 1400/06/19**
Registration timing: **retrospective**

Last update: **2021-09-10, 1400/06/19**
Update count: **0**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

sara zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4461 6943

Email address

sarazamaniaa@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-18, 1398/02/28

Expected recruitment end date

2020-01-18, 1398/10/28

Actual recruitment start date

2019-08-23, 1398/06/01

Actual recruitment end date

2020-08-22, 1399/06/01

Trial completion date

2020-10-22, 1399/08/01

Scientific title

Comparative study of the effect of two continuous epidural methods and continuous paravertebral block on pain after knee arthroplasty surgery

Public title

effect of continuous epidural and continuous paravertebral block on pain after knee arthroplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 40-70 years ASA I , II having the satisfaction of participating in the study

Exclusion criteria:

sensitivity to any of the drugs used in the study Body mass index>40 severe liver and heart disease addiction or prolonged use of analgesics

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **39**

Actual sample size reached: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two groups (n = 19) continuous epidural and continuous paravertebral block. Patients were completely randomly divided into four groups of continuous epidural receiving and continuous paravertebral block by Blocked Randomization method. Using the table of random numbers and quadratic blocks, the following conditions were obtained in which group A individuals received continuous epidural and group B individuals received continuous paravertebral block. Putting the four blocks together results in situations that are completely random and the patients are randomly divided.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind and hide the samples for each patient, a special code is written inside the sealed envelope, which is opened only before the patient is anesthetized and only by the researcher and in complete secrecy, and informs the patient group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of iran university of medical sciences

Street address

Jam e jam hemmattower Heidari moghadam St Sardar jangal Blvd

City

Tehran

Province

Tehran

Postal code

1476661349

Approval date

2020-04-03, 1399/01/15

Ethics committee reference number

IR.IUMS.FMD.REC.1397.175

Health conditions studied

1

Description of health condition studied

Degenerative joint disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain following joint changes leading to surgery and knee replacement

Timepoint

Immediately after the intervention 4 hours after the intervention 8 hours after the intervention 16 hours after the intervention 24 hours after the intervention

Method of measurement

Pain intensity with VAS scale numbered by a ruler on a scale of 0 to 10

Secondary outcomes

1

Description

Age

Timepoint

0

Method of measurement

Year

2

Description

Sex

Timepoint

0

Method of measurement

Male or female

3

Description

Weight

Timepoint

0

Method of measurement

Different number by kilogram

4

Description

Side effects of anesthesia

Timepoint

24 hours

Method of measurement

Patient symptoms

5

Description

Side effects of mepridine

Timepoint

24 hours

Method of measurement

Patient symptoms

6

Description

Amount of mepridine

Timepoint

24 hours

Method of measurement

By used dosage

Intervention groups

1

Description

Control group: Epidural block group In this trial, our treatment method was performed to reduce pain after knee replacement surgery.10 to 15 cc bupivacaine is 0.25%, which is injected epidurally.

Category

Treatment - Drugs

2

Description

Intervention group: Paravertebral block group is used as a treatment method to reduce pain after knee joint surgery.10 to 15 cc bupivacaine is 0.25% which is injected paravertebrally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool akram hospital

Full name of responsible person

Sara zamani

Street address

Jam e jam hemmat tower . heidari moghadam st . sardar jangal blvd

City

Tehran

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Postal code

1476661349

Phone

+98 21 4461 7095

Email

Sarazamaniaa@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas motevalian

Street address

Next to the milad tower . hemmat highway

City

Tehran

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Tehran

Postal code

1445613131

Phone

+98 21 8862 2675

Email

iumspr@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Sara zamani

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Student

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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
NO MORE DETAIL

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