

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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 .
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Tehran
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Postal code
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Phone
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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
Province
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

City

Tehran

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Phone

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Email

Sarazamaniaa@gmail.com

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 updating data

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Latest degree

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Other areas of specialty/work

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blvd

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