

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of spinal needle type on the incidence of Transient Neurologic Syndrom in spinal anesthesia.

Protocol summary

Study aim

Study of the effect of spinal needle type on the incidence of transient neurologic syndrom in spinal anesthesia

Design

This study is a triple-blinded clinical trial. The study population included all patients referring to lower limb surgery ward of Imam Reza hospital of Kermanshah city.

Settings and conduct

This study which will be conducted in Imam Reza hospital of Kermanshah city is triple-blinded one, that the participants, the researcher, and the evaluator will kept blinded to the intervention groups. Anesthesia segmentation level is measured by using cold-cottoned alcohol bilaterally every 5 minutes for 20 minutes and then every 15 minutes until the complete recovery, the sensory and motor block will be measured and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 18 and 60 years;ASA Class 1; BMI<25 Exclusion criteria: Taking opium; The presence of discopathy and chronic low back pain and previous lower limb pain

Intervention groups

In the first intervention group, anesthetic injections will be performed using the Quincke type G25 needle. Spinal anesthesia is injected in all patients in the L4 -L5 intervertebral lumbar region as the midline aperture, and after exiting, a small amount of CSF is injected with 0.5% bupivacaine at 12.5 mg/sec at 0.2 mg/sec In the second intervention group, anesthetic injections will be performed using the Sprutte type G25 needle. Spinal anesthesia is injected in all patients in the L4- L5 intervertebral lumbar region as the midline aperture, and after exiting, a small amount of CSF is injected with 0.5% bupivacaine at 12.5 mg/sec at 0.2 mg/sec.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100101002946N9**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6310

Email address

myari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-16, 1397/06/25

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of spinal needle type on the incidence of Transient Neurologic Syndrom in spinal anesthesia.

Public title

The effect of type of anesthetic needle on spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA Class 1 BMI<25 Aged between 18 and 60 years

Exclusion criteria:

Coagulation disorders Taking opium The presence of discopathy and chronic low back pain and previous lower limb pain Duration of operation more than 2 hours

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **150**

Actual sample size reached: **150**

More than 1 sample in each individual

Actual sample size in each individual:

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt. Selecting people randomly runs from one table point to the row or column by closing the eye and inserting a finger or pen tip on the table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients, investigator, and clinical caregiver will be blinded to the study groups, the drug dose, and the drug manufacturer. In fact, factors that could distort the test result are hidden from the eyes of the researcher, patients, and clinical caregivers.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.KUMS.REC.1397.005

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

Postoperative pain in orthopaedic lower limb surgery

ICD-10 code

M79.6

ICD-10 code description

Pain in limb, hand, foot, fingers and toes

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

Intensity of pain

Timepoint

The end of study

Method of measurement

Base on visual analog scale

Secondary outcomes

empty

Intervention groups**1****Description**

In the first intervention group, anesthetic injections will be performed using the Quincke type G25 needle. Spinal anesthesia is injected in all patients in the L4 -L5 intervertebral lumbar region as the midline aperture, and after exiting, a small amount of CSF is injected with 0.5% bupivacaine at 12.5 mg/sec at 0.2 mg/sec.

Category

Other

2**Description**

In the second intervention group, anesthetic injections

will be performed using the Sprutte type G25 needle.
Spinal anesthesia is injected in all patients in the L4- L5
intervertebral lumbar region as the midline aperture, and
after exiting, a small amount of CSF is injected with 0.5%
bupivacaine at 12.5 mg/sec at 0.2 mg/sec.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Somaye Ziaie

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

somaye.ziaie@yshoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Somaye Ziaie

Position

Residents Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

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Email

somaye.ziaie@yshoo.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mitra Yari

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Emam Reza Hospital, Parastar Boulevard

City

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Email

myari@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Somaye Ziaie

Position

Residents Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments