Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
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Dr. Mitra Yari
Position
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Latest degree
Specialist
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Person responsible for updating data

Contact

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Full name of responsible person
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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