# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jun 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**
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**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**
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**Province**
Kermanshah
**Postal code**
6715847141
**Phone**
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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**
Anesthesiology
**Street address**
Emam Reza Hospital, Parastar Boulevard
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## 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
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Specialist
**Other areas of specialty/work**
Anesthesiology
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Emam Reza Hospital, Parastar Boulevard
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## 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

**Street address**
Emam Reza Hospital, Parastar Boulevard

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**Province**
Kermanshah

**Postal code**
6715847141

**Phone**
+98 83 3427 6306

**Email**
somaye.ziaie@yshoo.com

## 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**