Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Spinal anesthesia with modified paramedian approach:copmarision with classic paramedian approach

Protocol summary

Study aim
Comparison of the consequences of modified paramedic spinal anesthesia with classical paramedin

Design
Clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, sample of 200 patients. Randlist software was used for randomization.

Settings and conduct
All patients who are candidates for spinal anesthesia in Imam Reza Hospital in Tabriz will be included in this study. Patients are randomly assigned to two groups of intervention and control. In the intervention group, the paramedic technique will be modified and in the control group, the classical paramedin will be applied to compare the consequences of these two techniques. In this study, the patient and one of the anesthesiologists and students who have a dissertation are blinded to the study.

Participants/Inclusion and exclusion criteria
Inclusion area: All patients aged 20 to 60 years are candidates for spinal anesthesia with ASA rating,grade 1&2. Exclusion area: Visible spinal deformity History of chronic or acute headache Emergency surgery Weight over 100 kg and height less than 50

Intervention groups
Intervention group:In this group,anesthesiologist in a sitting position from the L3-L4 or L4-L5 space with spinal needle No. 25 type Quincke at an angle of approximately 20-25 degrees to the medial until the tip of the needle reaches the subarachnoid space, depending on the duration of surgery 2-4 ml of bupivacaine 0.5% (manufactured by LES TOURS CEDEX-FRANCE) will be injected. Control group:In this group after finding the intervertebral space L3-L4 or L4-L5, by giving an angle of 10-15 to the medial and also an angle of10_15 towards the cephalic so that the tip of the needle reaches the subarachnoid.

Main outcome variables
Duration of successful block, patient satisfaction with the procedure, comfort of anesthesiologist, back pain during the procedure, post-block headache.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180518039700N2**
Registration date: **2020-08-06, 1399/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-06, 1399/05/16**
Update count: **0**

Registration date
2020-08-06, 1399/05/16

Registrant information

Name
Solmaz Fakhari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-30, 1399/04/10

Expected recruitment end date
2020-11-30, 1399/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Spinal anesthesia with modified paramedian approach:copmarision with classic paramedian approach

Public title
Comparison of Modified Paramedicine Spinal Anesthesia with Classic Paramedin

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
All patients aged 20 to 60 years are candidates for spinal anesthesia with ASA rating,grade 1&2. Body mass index less than 30

Exclusion criteria:
Visible spinal deformity History of chronic or acute headache Emergency surgery Weight over 100 kg and height less than 50 Surgery more than 3 hours

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients wishing to participate in the study who meet the inclusion criteria will be selected through convenient sampling and then randomly assigned to two control and intervention groups using Randlist software and blocks of size two.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, an anesthesiologist who is fully aware of the study will perform paramedic or classical paramedic techniques, then leave the operating room and during the operation, another anesthesiologist and anesthesia resident who is the owner of the dissertation are not aware of the applied technique. And only collect the data, the patient himself does not know the technique applied.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5183915881

Approval date
2020-06-29, 1399/04/09

Ethics committee reference number
IR.TBZMED.REC.1399.368

Health conditions studied

1

Description of health condition studied
Comparison of spinal anesthesia Paramedin modified paralysis and classical paramedin

ICD-10 code
T88.59

ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
Time to reach the successful block

Timepoint
From the start of the block attempt to the result

Method of measurement
In minutes

2

Description
Patient satisfaction with the procedure

Timepoint
After the operation

Method of measurement
Depending on the patient's questions (very low, low, high, very high)

3

Description
The comfort level of the anesthesiologist regarding the experience of the two techniques Paramedic Classic and Modified

Timepoint
After the operation

Method of measurement
Question from anesthesiologist (easier, more difficult, indifferent)

4

Description
Feeling of back pain while performing the procedure
Timepoint
From the beginning of the procedure to the end of the work
Method of measurement
Patient's own statements (no, mild, moderate, severe)

Secondary outcomes

1

Description
Headache after the block
Timepoint
6,12,24, 48 hours after the operation
Method of measurement
Patient's own statements (no, mild, moderate, severe)

Intervention groups

1

Description
Intervention group:In this group,anesthesiologist in a sitting position from the L3-L4 or L4-L5 space with the spinal needle with the thumb, the outer margin of the multifidus muscle, which is approximately one and a half centimeters lateral to the intervertebral space, is determined,then Insert spinal needle No. 25 type Quincke at an angle of approximately 20-25 degrees to the medial until the tip of the needle reaches the subarachnoid space, depending on the duration of surgery 2-4 ml of bupivacaine 0.5% (manufactured by LES TOURS CEDEX-FRANCE) will be injected.
Category
Treatment - Drugs

2

Description
Control group:In the classical paramedic method, after finding the intervertebral space L3-L4 or L4-L5, go one centimeter to the lateral and then 1 cm downwards and then by giving an angle of 10-15 to the medial and also an angle of10_15 towards the cephalic so that the tip of the needle reaches the subarachnoid.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Tabriz University of Medical Sciences
Full name of responsible person
Solmaz Fakhari
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Imam Reza Hospital, Golgasht St., Azadi Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Joiban
Street address
Faculty of Medicine, Tabriz University of Medical Sciences, Golghast St., Azadi Blvd.
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Solmaz Fakhari
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data can be shared after making peoples unrecognizable
When the data will become available and for how long
Starting 6 months after publication .
To whom data/document is available
Documents will be available for people working in academic institutions and also people working in businesses.
Under which criteria data/document could be used
There will be no specific limitations to the utilization of the data
From where data/document is obtainable
Dr .Solmaz Fakhari , Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 , solmaz_fakhari@yahoo.com
What processes are involved for a request to access data/document
Applicants will access the data from the present study by sending an email to the responsible author for a

maximum of one week.

Comments