

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Spinal anesthesia with modified paramedian approach: comparison 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 of 10\_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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3329 6124

##### Email address

fakharis@tbzmed.ac.ir

##### 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: comparison 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 of 10\_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

### Street address

Imam Reza Hospital, Golgasht St., Azadi Blvd.

### City

Tabriz

### Province

East Azarbaijan

### Postal code

5138947979

### Phone

+98 41 3334 1994

### Fax

+98 41 3334 1994

### Email

solmaz\_fakhari@yahoo.com

## 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.

#### City

Tabriz

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East Azarbaijan

#### Postal code

5165665931

#### Phone

+98 41 3335 7310

#### Fax

+98 41 3335 7310

#### Email

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

**Street address**

Imam Reza Hospital, Golgasht St., Azadi Blvd.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

Solmaz Fakhari

**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

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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**