

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Sprotte and Quincke Spinal Needles on the Frequency and Severity of Transient Neurologic Syndrome (TNS) after Spinal Anesthesia in Patients undergoing Cesarean Delivery

#### Protocol summary

##### Study aim

To compare Sprotte and Quincke spinal needles in the frequency and severity of transient neurologic syndrome after spinal anesthesia.

##### Design

After surgery, 160 patients will be selected as research sample and then divided into two groups of intervention and control. The intervention group will use Sprotte spinal needle and the control group will use Quincke spinal needle. The study is a randomized, double-blind, placebo-controlled clinical trial.

##### Settings and conduct

160 healthy pregnant women between ages of 18 to 40 and singleton pregnancy undergoing elective cesarean delivery receive spinal anesthesia using non-cutting Sprotte number 25 (study group; n=80) or cutting Quincke (control group; n=80) needles during 6 months in the Al-Zahra Hospital. The frequency and severity of transient neurologic syndrome are recorded after spinal anesthesia. Anesthesiologist is responsible for anesthesia management, and preparation of study solutions and the thesis student who is blinded to the study group is responsible for collecting information and data of patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Aged 18-40 years, ASA Class I&II, Term and singleton pregnancy, Exclusion criteria : Contraindication to spinal anesthesia, Allergy to local anesthetics Spinal cord stenosis and lumbar discopathy,

##### Intervention groups

Intervention group: this group (n=80) using of Sprotte (manufacturer: B brown) spinal needle G25 undergoing spinal anesthesia. Control group: this group (n=80) using of Quincke (manufacturer: B brown) spinal needle G25 undergoing spinal anesthesia

##### Main outcome variables

Evaluation of patients for TNS symptoms, onset and

duration of symptoms after anesthesia recovery, pain intensity based on VAS (from painless (0) to (10) to intolerable severe pain), type of treatment, and Dosage of analgesics

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110712007013N26**

Registration date: **2020-01-17, 1398/10/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

##### Registration date

2020-01-17, 1398/10/27

##### Registrant information

##### Name

Simin Atashkhoei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3806

##### Email address

atashkhoei@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-06-21, 1399/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Sprotte and Quincke Spinal Needles on the Frequency and Severity of Transient Neurologic Syndrome (TNS) after Spinal Anesthesia in Patients undergoing Cesarean Delivery

**Public title**

The effect of Sprotte or Quincke spinal needles on the frequency and severity of transient neurologic syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Candidate for elective cesarean delivery Candidate for spinal anesthesia Patients between 18-40 years ASA Class I&II Term and singleton pregnancy

**Exclusion criteria:**

Weight over 100 kg and height less than 150 cm Allergy to local anesthetics medicines History of psychiatric disease Spinal cord stenosis and lumbar discopathy History of systemic diseases (cardiovascular, hepatic, pulmonary, ...)

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

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

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In present study, patients, investigator, care provider, outcome assessor and data analyzer are blinded to participants study groups. The study team includes an anesthesiologists, who is responsible for data collection and outcome assessing, who is not in charge of anesthesia management, thus is not aware of interventions and study group. In addition, all study groups and subsequent interventions will be introduced to the patients and it will be mentioned in the written consent that patients will be blinded to the study groups

and interventions .Patients are allocated into study and control groups, according to a two blocked randomization list that is prepared using online software at a 1:1 ratio. The list is coded (A or B) that is preprinted in sealed-envelope packets. Except for one of anesthetists, all of researchers are blinded to the type of spinal needle for every patient during the study

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics 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**

2019-12-09, 1398/09/18

**Ethics committee reference number**

IR.TBZMED.REC.1398.971

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

The effect of Sprotte and Quincke spinal needles on the frequency and severity of neurological syndrome

**ICD-10 code**

O74.6

**ICD-10 code description**

Other complications of spinal and epidural anesthesia during labor and delivery

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

Time of onset of symptoms of transient neurological syndrome

**Timepoint**

6 to 48 hours after surgery

**Method of measurement**

Physical examination

## 2

### **Description**

Duration of symptoms of transient neurological syndrome after recovery from anesthesia

### **Timepoint**

6 to 48 hours after surgery

### **Method of measurement**

Physical examination

## 3

### **Description**

Severity of pain caused by transient neurological syndrome

### **Timepoint**

6 to 48 hours after surgery

### **Method of measurement**

Similar verbal scoring

## **Secondary outcomes**

## 1

### **Description**

Type of treatment used for transient neurological syndrome

### **Timepoint**

6 to 48 hours after surgery

### **Method of measurement**

Clinical record

## 2

### **Description**

The dose of treatment used to treat transient neurological syndrome

### **Timepoint**

6 to 48 hours after surgery

### **Method of measurement**

Clinical record

## **Intervention groups**

## 1

### **Description**

Intervention group: The patients of this group (n=80) using of Sprotte( manufacturer: B brown) spinal needle G25 undergoing spinal anesthesia.

### **Category**

Treatment - Devices

## 2

### **Description**

Control group: The patients of this group (n=80) using of Quincke ( manufacturer: B brown)spinal needle G25 undergoing spinal anesthesia

### **Category**

Treatment - Devices

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Al-Zahra Hospital

#### **Full name of responsible person**

Dr. Simin Atashkhoyi

#### **Street address**

Al-Zahra Hospital , South Artesh Street, Tabriz

#### **City**

Tabriz

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#### **Postal code**

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#### **Phone**

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#### **Email**

satashkhoyi@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tabriz University of Medical Sciences

#### **Full name of responsible person**

Dr Abolghasem Jouyban

#### **Street address**

Research and innovation deputy, third floor, No 2  
Central Building, Tabriz University of Medical  
Sciences, Goltasht Street, Tabriz

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#### **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**

Dr. Simin Atashkhoyi

**Position**

Anesthesiologist/ Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

A portion of the data that represents the final outcome

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

All Physicians and residents of the department of Anesthesia

**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 .Simin Atashkhoei Al-Zahra Hospital South Artesh Street, Al-Zahra Hospital, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 41 1553 9161 Fax+98 41 1556 6449 siminatashkhoei@yahoo.com

**What processes are involved for a request to access**

**data/document**

Be approved by the Research Vice-President at first  
**Comments**