Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Siences

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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 been 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Abolghasem Jouyban
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Research and innovation deputy, third floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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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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Person responsible for updating data

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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 siminatashkhoii@yahoo.com
What processes are involved for a request to access

data/document	Be approved by the Research Vice-President at first
Comments	