Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Sprotte and Quincke spinal needles on the frequency of spinal anesthesia failure in patients undergoing cesarean delivery

Protocol summary

Study aim

The aim of this study is the comparison of Sprotte and Quincke spinal needles on the frequency of spinal anesthesia failure in patients undergoing cesarean delivery.

Design

Clinical trial with community-based and pragmatic control group, with parallel groups, double blind, randomized.

Settings and conduct

In this prospective and randomized study ,100 healthy pregnant women between ages of 18to40 and singleton pregnancy undergoing elective cesarean delivery receive spinal anesthesia using non-cutting Sprotte (study group; n=50) or cutting Quincke (control group; n=50) needles during 6 months in the Al-Zahra Hospital. The frequency of “overall“ and “partial” failure of spinal block and and post operated side effects related to spinal anesthesia are recorded. anesthesiologist is responsible for anesthesia management, patient monitoring, 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 : Candidate for elective cesarean delivery, Aged 18-40 years, ASA Class I&II, Term and singleton pregnancy, Exclusion criteria : Contraindication to spinal anesthesia, Allergy to local anesthetics, History of psychiatric disease, History of systemic diseases (cardiovascular, hepatic, pulmonary, ...), Spinal cord stenosis and lumbar discopathy,

Intervention groups

Intervention group: The patients of study group (n=50) using of Sprotte spinal needle G25(manufacturer: B brown) undergoing spinal anesthesia and the patients of control group (n=50) using of Quincke spinal needle G25 (manufacturer: B brown)undergoing spinal anesthesia.

Main outcome variables

Frequency of “overall“ and “partial” failure of spinal block and postoperative side effects related to spinal anesthesia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110712007013N25**
Registration date: **2019-12-21, 1398/09/30**
Registration timing: **retrospective**

Last update: **2019-12-21, 1398/09/30**
Update count: **0**

Registration date

2019-12-21, 1398/09/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2019-12-01, 1398/09/10

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 of spinal anesthesia failure in patients undergoing cesarean delivery

Public title

Comparison of Sprotte and Quincke spinal needles on the frequency of spinal anesthesia failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for elective cesarean delivery Candidate for spinal anesthesia Aged 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 History of psychiatric disease History of systemic diseases (cardiovascular, hepatic, pulmonary, ...) Spinal cord stenosis and lumbar discopathy

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

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

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Province

East Azarbaijan

Postal code

5183915881

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.TBZMED.REC.1398.390

Health conditions studied

1

Description of health condition studied

Frequency of spinal anesthesia failure

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description

Frequency of “overall failure“ of spinal block

Timepoint

At the beginning of the intervention and in 5th,10th and 15th minutes after the intervention

Method of measurement

Cold sensation

2

Description

Frequency of partial failure“ of spinal block

Timepoint

At the beginning of the intervention and in 5th,10th and 15th minutes after the intervention

Method of measurement

Cold sensation

Secondary outcomes

1

Description

postoperative side effects related to spinal anesthesia.

Timepoint

Post anesthesia care unite, and during 24 hours postoperatively

Method of measurement

Observational

Intervention groups

1

Description

Intervention group: The patients of study group (n=50) using of Sprotte(manufacturer: B brown) spinal needle G25 undergoing spinal anesthesia.

Category

Treatment - Devices

2

Description

Control group: The patients of control group (n=50) 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

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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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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