Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of 22-gauge and 25-gauge spinal needles on the incidence, severity, and duration of post-dural puncture headache in women undergoing elective cesarean section: A randomized controlled trial in Naseriaeh, Iraq

Protocol summary

Study aim

Comparison of 22 gauge and 25 gauge spinal needles on the incidence, severity, and duration of post-dural puncture headache in women undergoing elective cesarean section

Design

This controlled, parallel-group, double-blinded, randomized phase 3 trial will include 48 women. Randomization will use computer-generated block sequences with allocation concealment.

Settings and conduct

The study will be conducted at the Department of Anesthesiology, Al-Habobi Hospital, Nasiriyah, Iraq. The anesthesiologist cannot be blinded, but participants and outcome assessors will be. The intervention group will receive spinal anesthesia with a 25-gauge needle, and the control group with a 22-gauge needle. All participants will receive standard postoperative analgesia and be monitored daily for five days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-45 years, scheduled for elective cesarean section, ASA I–II, singleton pregnancy, and eligible for spinal anesthesia Exclusion criteria: History of headache or post-dural puncture headache, contraindications to spinal anesthesia, spinal deformity or prior spinal surgery, multiple pregnancy, BMI > 40 kg/m², and known neurological disorders.

Intervention groups

All participants will receive standard perioperative care, and spinal anesthesia will be administered following a standardized protocol. They will be randomly assigned to one of two groups: Group A will receive spinal anesthesia using a 22-gauge needle, and Group B using a 25-gauge needle.

Main outcome variables

Primary outcome: Incidence of post-dural puncture headache within five days. Secondary outcomes: Post-dural puncture headache severity, onset time of post-dural puncture headache, and procedure-related adverse effects within five days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130803014251N11**
Registration date: **2026-05-16, 1405/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-16, 1405/02/26**
Update count: **0**

Registration date

2026-05-16, 1405/02/26

Registrant information

Name

MORTEZA NASIRI

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 2622 5292

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-10, 1405/02/20

Expected recruitment end date

2026-07-21, 1405/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 22-gauge and 25-gauge spinal needles on the incidence, severity, and duration of post-dural puncture headache in women undergoing elective cesarean section: A randomized controlled trial in Naseriaeh, Iraq

Public title

Effect of spinal needle size on headache after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18-45 years Scheduled for elective C/S American Society of Anaesthesiologists (ASA) grade I or II Singleton pregnancy Eligible for spinal anesthesia Successful spinal anesthesia on first needle insertion Ability to understand and provide written informed consent

Exclusion criteria:

History of headache disorders within the past six months, such as migraine or tension-type headache Any history of PDPH Contraindications to neuraxial anesthesia (e.g., coagulopathy, soft tissue infections at the needle insertion site, severe hypovolemia) Spinal deformity or previous spinal surgery Multiple pregnancy Body mass index greater than 40 kilograms per square meter Known neurological disorders (e.g., seizures)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

After consent, participants will be randomized 1:1 to the needle size 22 or 25 group using a computer-generated random sequence. Block randomization (blocks of 4 or 6) will be used to maintain balance. Allocation will be concealed using sealed opaque envelopes; the envelope will be opened only at the time of the spinal procedure.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist performing the spinal block cannot be blinded due to the nature of the intervention. However, participants and all outcome assessors will remain blinded to the needle gauge to minimize detection and performance bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Public Health & Allied Medical Sciences of Tehran University

Street address

Building of Health School of Tehran University of Medical Sciences, Poursina Alley, Ghods Street, Enghelab Street, Tehran Province, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417744361

Approval date

2026-12-10, 1405/09/19

Ethics committee reference number

IR.TUMS.SPH.REC.1405.052

Health conditions studied

1

Description of health condition studied

Post-dural puncture headache

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of post-dural puncture headache

Timepoint

Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.

Method of measurement

International Classification of Headache Disorders (ICHD) criteria

Secondary outcomes

1

Description
Severity of post-dural puncture headache
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
Visual Analog Scale

2

Description
Onset time of post-dural puncture headache
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
A structured postoperative follow-up form

3

Description
Adverse effects of the intervention
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
A structured postoperative follow-up form

Intervention groups

1

Description
Intervention group: In the intervention group, spinal anesthesia will be performed using a 25-gauge Quincke needle.
Category
Prevention

2

Description
Control group: In the control group, spinal anesthesia will be performed using a 22-gauge Quincke needle.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Habobi Hospital
Full name of responsible person
Humam Younus Manea Alaskari
Street address
Al-Habobi Street, Nasiriyah, Dhi Qar Governorate, Iraq
City
Nasiriyah
Postal code
64001–64199
Phone
+964 1 770 4255
Email
info@moh.gov.iq
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Nabi Shariati Far
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Postal code
1417653761
Phone
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Email
tumspr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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Full name of responsible person
Dr. Morteza Nasiri
Position
Assistant Professor

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Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only a part of patients' demographical data and main outcomes will be shared.
When the data will become available and for how long
After the publishing of the results
To whom data/document is available
Data will be available only for researchers working on academic and university associations.
Under which criteria data/document could be used
Mention of study details and authors name
From where data/document is obtainable
Dr. Morteza Nasiri: Department of Operating Room, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran
What processes are involved for a request to access data/document
Information will provide via the following email upon request. Mortezanasiri.or87@yahoo.com
Comments