Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of post-dural puncture headache after paramedian approach versus Taylor's approach

Protocol summary

Study aim
Comparison of post-dural puncture headache after paramedian approach versus Taylors approach

Design
In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 370 patients who will be undergoing elective cesarean section under spinal anesthesia will be enrolled. Eligible Patients will be assigned randomly to tow groups using computer-generated random sequence numbers (www.randomization.org).

Settings and conduct
This study will be done in recovery and ward of Ghadir Mother and Child Hospital in Shiraz. After the intervention, the patients will be assessed in terms of headache by someone unaware of spinal approach on days 1 and 2 once a day and on days 3, 5 and 7 by telephone interview using a questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: we will study all patients aged 18-44 years with the American Society of Anesthesiologists physical status I/II term pregnant women, who will undergo elective cesarean delivery under spinal anesthesia. Exclusion criteria: Adult women with ASA grade III or IV, Patients with a history of more than 3 times cesarean section, Hemodynamic instability, Bleeding diathesis or coagulopathy, Chronic headache

Intervention groups
Intervention group P: In the Paramedian approach, patients will be placed in the sitting position and a 27-gauge spinal needle is inserted into the subarachnoid space at an angle of 10-15 degrees in the spaces between L3-4 or L4-5, and then the cephalad is guided. Intervention group T: Taylor's approach technique will be carried out at the L۵-S۱ inter space, the largest interlaminar inter space of the vertebral column. A 27-gauge spinal needle will be inserted in a cephalo-medial direction through a skin wheel raised ۱ cm medial and ۱ cm caudal to the lowermost prominence of the posterior iliac spine.

Main outcome variables
Postdural puncture headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091117002723N2**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **prospective**

Last update: **2023-02-07, 1401/11/18**
Update count: **0**

Registration date
2023-02-07, 1401/11/18

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
07112337636

Email address
hadavimr@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10

Expected recruitment end date
2023-11-01, 1402/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of post-dural puncture headache after paramedian approach versus Taylor's approach

Public title
Effects of two spinal anesthesia approaches in the Prevalence of headache after operation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Women having elective caesarean section under spinal anesthesia Women between 18 and 44 years old Adult women with ASA grade I or II (American Society of Anesthesiology classification)

Exclusion criteria:
Adult women with ASA grade III or IV (American Society of Anesthesiology classification) Patients with a history of more than 3 times cesarean section Pregnancy Induced Hypertension Hemodynamic instability Bleeding diathesis or coagulopathy Chronic headache Patients with local infection in the lumbar region

Age
From **18 years** old to **44 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **370**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned randomly to tow groups using computer-generated random sequence numbers (www.randomization.org). Sealed envelopes will be used to conceal the allocation sequence. Group P will include patients who will undergo spinal anesthesia by a cutting 27-gauge spinal needle with a paramedian approach. Group T will include patients who will undergo spinal anesthesia by a cutting 27-gauge spinal needle with Taylor's approach.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in the study and those who follow up the participants do not know the method of spinal procedure and the specialist performs the spinal anesthesia based on the random sequence table.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz Medical School

Street address
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2022-12-03, 1401/09/12

Ethics committee reference number
IR.SUMS.REC.1401.587

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
O82

ICD-10 code description
Encounter for cesarean delivery without indication

Primary outcomes

1

Description
Headache

Timepoint
Up to 7 days after surgery

Method of measurement
Severity of Postdural puncture headache will be graded by a score described by Lybecker et al

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group P: In the Paramedian approach, patients will be placed in the sitting position and a 27-gauge spinal needle is inserted into the subarachnoid space at an angle of 10-15 degrees in the spaces between L3-4 or L4-5, and then the cephalad is guided.

Category
Prevention

2

Description
Intervention group T: Taylor's approach technique will be carried out at the L۵-S۱ inter space, the largest inter laminar inter space of the vertebral column. A spinal needle will be inserted in a cephalo-medial direction through a skin wheel raised ۱ cm medial and ۱ cm caudal to the lowermost prominence of the posterior iliac spine.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghadir Mother and Child Hospital
Full name of responsible person
Mahsa Tahvili
Street address
Ghadir Mother and Child Hospital, the beginning of Golshan town, above the Quran gate.
City
Shiraz
Province
Fars
Postal code
۷۱۴۴۹۹۵۴۷۷
Phone
+98 71 3227 9701
Fax
Email
Motherhosp@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpoor
Street address
7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3235 7282
Fax
+98 71 3212 2430
Email
memarpour@sums.ac.ir
Web page address
https://rde.sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mahsa Tahvili
Position
physician /anesthesiology fellowship
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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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Position
Assistant Professor of Pain Anesthesiology
Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamide Saeedizade
Position
Research Assistant
Latest degree
Bachelor
Other areas of specialty/work
Medical Informatics
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Postal code
7134844119
Phone
0098-36281460
Email
saeedi.hamide@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It is against our policy.
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available