

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 Taylor's 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 two 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 L0-S1 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 1 cm medial and 1 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 two 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 building 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 L4-S1 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 1 cm medial and 1 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

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Fars

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7142995377

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 Memarpour

Street address

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street

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Email

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Web page address

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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

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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Anesthesiology Department, Faghihi Hospital, Zand Street.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Mohammad Reza Hadavi

Position

Assistant Professor of Pain Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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

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

Street address