Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment PDPH in women under elective cesarean section with two types of spinal needles

Protocol summary

Study aim
Evaluation of the effect of two types of Quincke and Whitaker needles on the incidence and severity of postdural puncture headache (PDPH) in women candidates for elective cesarean section under spinal block in Rafsanjan in 1399

Design
A clinical trial with a control group, two parallel groups, single-blind, randomized based on a random number table, and according to the number of patients entering the study was performed on 130 patients.

Settings and conduct
Field of work: Women candidates for elective cesarean section, Rafsanjan Women's Training Hospital. How to do: Follow up women after elective cesarean section for up to one week for the occurrence and severity of the postural headache and also evaluate accompanying symptoms such as shoulder pain, photophobia until one week after cesarean section, single blinding of participants

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women candidates for elective cesarean section under spinal anesthesia who have completed the informed consent form to participate in the study. 2. Age range 15 to 45 years Exclusion criteria: 1- Women whose spinal anesthesia fails for the first time for any reason or partial anesthesia and we have to use analgesics and hypnotics to continue the operation. 2. Women taking anticoagulants or high blood pressure

Intervention groups
Intervention group 1: Quincke needle. Intervention group 2: Whitaker needle.

Main outcome variables
Postdural puncture headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190817044544N2**
Registration date: **2022-01-13, 1400/10/23**
Registration timing: **retrospective**

Last update: **2022-01-13, 1400/10/23**
Update count: **0**

Registration date
2022-01-13, 1400/10/23

Registrant information

Name
Fatemeh Jadidi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
2020-07-22, 1399/05/01

Actual recruitment end date
2021-07-23, 1400/05/01

Trial completion date
empty

Scientific title
Assessment PDPH in women under elective cesarean section with two types of spinal needles

Public title

Postdural puncture headache

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Elective cesarean section women with ASA class1

Exclusion criteria:

Women candidates for emergency cesarean section and underlying disease

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **130**

Actual sample size reached: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using the excel file and random between function, 65 numbers were randomly selected from the numbers 1-130, which were assigned to the intervention group and the remaining numbers to the control group, then according to the number of women entering the study, the type of her group A (intervention) or B (control) was determined

Blinding (investigator's opinion)

Single blinded

Blinding description

For the participants in the study, the complication of postural puncture headache is explained and it said that two types of needles are used in this study, but each participant does not know the type of needle specifically.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Emam Ali Blvd., Main building of Medical sciences University

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2020-05-23, 1399/03/03

Ethics committee reference number

IR.RUMS.REC.1399.041

Health conditions studied

1

Description of health condition studied

PDPH in elective cesarean surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of Postdural puncture headache

Timepoint

During the first 7 days after the intervention, the evaluation is performed every day

Method of measurement

In case of PDPH after spinal anesthesia, it is stated in the questionnaire form

Secondary outcomes

1

Description

severity of PDPH after spinal anesthesia

Timepoint

It is evaluated daily for seven days after cesarean section

Method of measurement

Visual analogue scale

2

Description

Days of PDPH

Timepoint

During seven days follow up after spinal block how many days PDPH occurs

Method of measurement

In case of this type of headache, complete the questionnaire on the number of days of PDPH

3

Description

If PDPH occurs after spinal anesthesia, it is necessary to take analgesic within seven days or not

Timepoint

During seven days follow up after spinal block,In case of PDPH، number of times the need for analgesic in total is

evaluated

Method of measurement

The number of times the need for analgesic during seven days is recorded in the questionnaire

4

Description

there is restriction of movement in sleeping to sitting or sitting to standing

Timepoint

During seven days of follow up of PDPH

Method of measurement

The questionnaire completes the movement restriction section

5

Description

Is there associated symptoms and signs Includes neck pain, shoulder pain, nausea, sensitivity to sound, light

Timepoint

follow up during seven days after spinaL block

Method of measurement

In the questionnaire, the items are recorded in case of occurrence

Intervention groups

1

Description

Intervention group: Intervention group: Women under spinal anesthesia for elective cesarean section with Whitaker needle 25،needle insertion technique: Paramedin

Category

Other

2

Description

Control group: Women candidates for elective cesarean section under spinal anesthesia with Quincke 25 needle, Paramedin needle insertion technique

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Ebn Abitaleb Hospital of Rafsanjan

Full name of responsible person

Fatemeh Jadidi

Street address

Ali-Ebn Abitaleb square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

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?

No

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Fatemeh Jadidi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Participants' personal data can be shared after not being identified
When the data will become available and for how long
Access period starts six months after the results are published
To whom data/document is available
Academic researchers and industry professionals can apply for the data
Under which criteria data/document could be used
In case of data reference, their use is unrestricted
From where data/document is obtainable
Rafsanjan University of Medical Sciences
What processes are involved for a request to access data/document
permission of vise chancellor of research and technology of RUMS
Comments