Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

The effect of Head elevation after spinal anesthesia on hemodynamic and sensory block height during elective cesarean delivery in pregnant women referred to Maryam Hospital

Protocol summary

Study aim

The effect of Head elevation after spinal anesthesia on hemodynamic and sensory block height during elective cesarean delivery

Design

A randomized clinical trial, two groups of 30; intervention: Spinal anesthesia by raising the patient's head 30 degrees and control Spinal anesthesia without raising the patient's head, randomized using the random numbers table.

Settings and conduct

Pregnant women candidates for elective cesarean section referred to Maryam Hospital with the conditions of entry into the study will be randomly placed in two groups of 30 in one of the intervention/control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with consent to participate in the project; Pregnant women with ASA Class I, II ; Gestation age 39-37 weeks; Singleton. Exclusion criteria: Pregnant women with lack of consent to participate in the project; Diseases related to pregnancy such as gestational hypertension; preeclampsia; gestational diabetes; Multiple births; Known fetal anomaly; Local infection; History of drug abuse; People who are unable to maintain the position when the needle is inserted; History of spine surgery Presence of wound and infection at the needle entry site.

Intervention groups

Intervention group: For spinal anesthesia, a simple pillow is used for the patient and the patient's head is raised 30 degrees. Control group: Spinal anesthesia is performed without raising the patient's head.

Main outcome variables

The height of the sensory block, Maternal hemodynamic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211112053042N3**
Registration date: **2022-09-17, 1401/06/26**
Registration timing: **prospective**

Last update: **2022-09-17, 1401/06/26**
Update count: **0**

Registration date

2022-09-17, 1401/06/26

Registrant information

Name

Mohammad Hossein Delshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3350 2347

Email address

m.delshad@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-01, 1401/07/09

Expected recruitment end date

2023-01-19, 1401/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Head elevation after spinal anesthesia on hemodynamic and sensory block height during elective cesarean delivery in pregnant women referred to Maryam Hospital

Public title
The effect of raising the head after spinal anesthesia on blood pressure and level of anesthesia in elective cesarean delivery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with consent to participate in the project Pregnant women with ASA Class I, II Gestation age 39-37 weeks Singleton

Exclusion criteria:
Pregnant women with lack of consent to participate in the project Diseases related to pregnancy such as gestational hypertension, preeclampsia, gestational diabetes Multiple births Known fetal anomaly Local infection History of drug abuse People who are unable to maintain the position when the needle is inserted History of spine surgery Presence of wound and infection at the needle entry site

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Study subjects will be divided into two groups, control and intervention, using a simple randomization method and using a table of random numbers. First, each person is assigned a number. Then, using the table of random numbers, each selected number is randomly assigned to one of the groups, and this work continues until the number of people in each group is completed. Therefore, the researcher will not have the authority to change the status of the assignment of people or to predict it. Randomization concealment will be done by a third person who does not participate in other stages of the intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Alborz University of Medical Sciences

Street address
second floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City
Karaj

Province
Alborz

Postal code
3149779453

Approval date
2022-06-24, 1401/04/03

Ethics committee reference number
IR.ABZUMS.REC.1401.082

Health conditions studied

1

Description of health condition studied
Spinal anesthesia

ICD-10 code
O89. 4

ICD-10 code description
Spinal and epidural anesthesia

Primary outcomes

1

Description
The height of the sensory block

Timepoint
Every 5 minutes from the time of spinal injection until the embryo is removed and the end of the surgery

Method of measurement
By pinprick test

Secondary outcomes

1

Description
Systolic blood pressure

Timepoint
Every minute from the time of spinal injection until the fetus is removed and then every 5 minutes

Method of measurement
Measurement with pressure gauge

2

Description
Diastolic blood pressure
Timepoint
Every minute from the time of spinal injection until the fetus is removed and then every 5 minutes
Method of measurement
Measurement with pressure gauge

3

Description
Heart rate
Timepoint
Every minute from the time of spinal injection until the fetus is removed and then every 5 minutes
Method of measurement
Measurement with non-invasive devices

4

Description
Oxygen saturation
Timepoint
Every minute from the time of spinal injection until the fetus is removed and then every 5 minutes
Method of measurement
Pulse Oximetry

5

Description
Maternal complications
Timepoint
Every minute from the time of spinal injection until the fetus is removed
Method of measurement
Doctor's diagnosis

6

Description
Apgar score
Timepoint
At 1 and 5 minutes after birth
Method of measurement
Neonatal specialist examination

Intervention groups

1

Description
Intervention group: Spinal anesthesia is performed in the sitting position from the L2-L3 or L3-L4 spaces with the Midline approach using a Quincke needle 25 gage and 8-12 ml of 0.1% ropivacaine. The patient's head is elevated 30 degrees with a simple pillow.
Category
Prevention

2

Description
Control group: Spinal anesthesia is performed like the intervention group without elevating the patient's head.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Maryam Hospital
Full name of responsible person
Mohammad Hossein Delshad MD.
Street address
Arghvan West, 45 meter Golshahr St.
City
Karaj
Province
Alborz
Postal code
3198683639
Phone
+98 26 3350 9323
Email
m.delshad@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hatam Godini P.H.D
Street address
Saffarian alley, 45 meters from Golshahr, Karaj
City
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3198764653
Phone
+98 26 3464 3705
Email
h.godini@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Hossein Delshad MD.
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Arghavan Gharbi, 45 meters from Golshahr Street, Karaj, Alborz Province
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Person responsible for scientific inquiries

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Karaj University of Medical Sciences
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
Research centers and faculty members
Under which criteria data/document could be used
At the request of the researcher and faculty members
From where data/document is obtainable
Send email to the scientific respondent
What processes are involved for a request to access data/document
Within two months from the time of requesting and sending the email, the documents will be sent to the

mentioned people

Comments