Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the duration of spinal anesthesia in elective cesarean section in Trendelenburg and reverse Trendelenburg positions

Protocol summary

Study aim
Comparison of the duration of spinal anesthesia in elective caesarean section candidates in Trendelenburg and Reverse Trendelenburg positions in Kamali Hospital

Design
Randomized clinical trial without control group, with parallel groups, without blinding, on 60 patients. For randomization, the samples are assigned to two groups using the block randomization method with unequal block sizes (4,6,8).

Settings and conduct
The number of samples is 60 patients who will be randomly divided into two groups of 30 people. After receiving spinal anesthesia, the first group will be placed in the 10-degree Trellandenberg position, and the second group will be placed in the 10-degree reverse Trellandenberg position after receiving spinal anesthesia. The duration of spinal anesthesia in minutes will be recorded and compared in two groups.

Participants/Inclusion and exclusion criteria
Age 20-45, height range 155-170 cm and ASAII will be performed. Termination of pregnancy should be during term (37-42 weeks). The patient should undergo spinal anesthesia. The pregnant mother has not used any special drugs. The pregnant mother does not have any underlying disease. The mother does not have any drug addiction. BMI should be less than 30.

Intervention groups
Trendelenburg and reverse Trendelenburg positions

Main outcome variables
1) Duration of spinal anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211228053560N1**
Registration date: **2022-12-29, 1401/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-29, 1401/10/08**
Update count: **0**

Registration date
2022-12-29, 1401/10/08

Registrant information

Name
susan Rahimi

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
2022-12-21, 1401/09/30

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the duration of spinal anesthesia in elective cesarean section in Trendelenburg and reverse Trendelenburg positions

Public title
Comparison of the duration of spinal anesthesia in Trendelenburg and reverse Trendelenburg positions

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The study will be conducted on people aged 20-45 Height range 155-170 cm and ASAII Termination of pregnancy should be during the term (37-42 weeks). The patient should undergo spinal anesthesia. The pregnant mother has not used any special drugs. The pregnant mother does not have any underlying disease. The mother does not have any drug addiction BMI is less than 30
Exclusion criteria:
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In block randomization, in order to hide the allocation process, which is the most important principle in randomized clinical trials, the size of the blocks is considered unequal. Blocking is used in order to balance the number of samples allocated to each of the studied groups. This feature helps researchers to ensure that the number of samples allocated to each of the study groups is equal in cases where intermediate analyzes are needed during the sampling process. Blocking is done in two ways: in the first method, the size of all blocks is equal (for example, in a two-group experiment, blocks of 8 including 4 participants in the intervention group and 4 participants in the control group) and in the second method, the size of the block are randomly selected (for example: blocks of 8, 6, 10 and 14 in which there are equal numbers of each group in each block).The purpose of block randomization is to make sure that an equal number of participants enter the intervention and control groups at consecutive but equal time intervals.The samples will be randomly assigned to one of two groups. For randomization, the block randomization method with unequal block sizes (4, 6, and 8 blocks) will be used {to equalize the volume of samples in two groups and hide the allocation process}. To prepare the list, the web software at the following internet address will be used (by giving the required inputs, including the total sample size and the size of the blocks). This list is only in the hands of the researcher who has no role in the allocation and evaluation of the results.In this method, each random sequence is created and recorded on a card, and the cards are placed in the envelopes in order. In order to maintain a random sequence, the numbering on the outer surface of the envelopes is done in the same order and it is pasted in the letter envelopes and placed inside a box. At the beginning of the registration of the participants, one of the letter envelopes, the flow of the order of entry of the qualified participants into the study, will be opened and the time group of that company will be revealed.
https://www.sealedenvelope.com/simple-randomiser/v1/lists
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
No. 4 , Pardis builing , second west Laleh , Boostan 14 Ave. , Baqestan , Karaj
City
karaj
Province
Alborz
Postal code
3194874714
Approval date
2022-09-13, 1401/06/22
Ethics committee reference number
IR.ABZUMS.REC.1401.147

Health conditions studied

1

Description of health condition studied
Comparison of the duration of spinal anesthesia in elective caesarean section candidates in Trendelenburg and Reverse Trendelenburg positions
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Duration of spinal anesthesia
Timepoint
After receiving spinal anesthesia, the first group is placed in the 10-degree Trendelenberg position and the second group is placed in the 10-degree reverse Trendelenberg position. The duration of spinal anesthesia from the time

when the movement of the leg is completely stopped and disturbed every 15 minutes, until the time when he can fully bend his knee in minutes, will be recorded and compared by the researcher in two groups. The level of spinal anesthesia based on the dermatome will be recorded in both groups before the cesarean section and every 15 minutes during recovery until the patient can fully bend the knee.

Method of measurement

The duration of spinal anesthesia from the time when the leg movement is completely stopped and impaired until he can fully bend his knee in minutes will be recorded and compared by the researcher in two groups.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group is placed in the 10-degree Trendelenberg position after receiving spinal anesthesia. Then patients receive 3cc of 0.5% aspen hyperbaric marcaine through Dr. Japan Co. Ltd. spinal needle No. 25 in the third and fourth lumbar space in the sitting position. The injection should be done by one person and with only one try. The duration of spinal anesthesia from the time when the movement of the leg is completely stopped and disturbed until he can fully bend his knee in minutes, in this group by the researcher It will be recorded and compared with the other group. The level of spinal anesthesia will be recorded and compared according to the dermatome before the cesarean section and every 15 minutes during recovery in both groups. To ensure the removal of anesthesia, Broomage criteria will be used. Also, during this period, the baby's blood pressure, heart rate, arterial oxygen saturation and Apgar will be recorded.

Category

Treatment - Other

2

Description

Intervention group: After receiving spinal anesthesia, the second group is placed in a 10-degree inverted Trendelenburg position. Then, the patients receive 3cc of 0.5% aspen hyperbaric marcaine through a Dr.Japan Co.Ltd spinal needle No. 25 in the third space and They receive a fourth lumbar in the sitting position. The injection should be done by one person and with only one try. The duration of spinal anesthesia from the time when the movement of the leg is completely stopped and disturbed until he can fully bend his knee in minutes, in this group by the researcher It will be recorded and compared with the other group. The level of spinal anesthesia will be recorded and compared according to the dermatome before the cesarean section and every 15 minutes during recovery in both groups. To ensure the removal of anesthesia, Broomage criteria will be used. Also, during this period, the baby's blood pressure, heart rate, arterial oxygen saturation and Apgar will be recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
kamali Hospital

Full name of responsible person
Banafshe mashak

Street address
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3134877179

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
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Street 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
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

susan rahimi

Position

intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Latest degree

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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

Undecided - It is not yet known if there will be 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

All the data and results of the study will be available after de-identification as a thesis in the library resource of Alborz University of Medical Sciences.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It can be used in line with humanitarian goals and the advancement of science

From where data/document is obtainable

Alborz University of Medical Sciences

What processes are involved for a request to access data/document

After joining the electronic library of Alborz University of Medical Sciences, access is immediately free.

Comments