Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Use of squatting position for facilitating of spinal block performance in patients undergoing cesarean

Protocol summary

Study aim
The aim of this study was to evaluate the effect of using a squatting position to facilitate spinal block in patients undergoing cesarean section.

Design
Clinical trial, randomized, double blinded with parallel groups on 120 patients

Settings and conduct
The present study was performed in Al-Zahra Hospital in Tabriz. The study is a double-blind study in which the study data was performed by a student and a respected midwife expert who was unaware of the study. Spinal block and patients were monitored by an anesthesiologist and an anesthesia resident.

Participants/Inclusion and exclusion criteria
Patients with ASA class one or two, single-term pregnancy, body mass index below 35 kg/m2, and candidate for elective cesarean section are included in the study. Patients with conscious reluctance to enter the study, candidate for emergency cesarean section, history of spinal surgery or spinal deformity including scoliosis, kyphosis and lordosis, and contraindications to spinal anesthesia are excluded from the study.

Intervention groups
Intervention group: In a squatting position, spinal anesthesia with Quinke needle No. 25 from the inter-vertebral space L2-3 or L3-4 in the midline approach with bupivacaine 0.5% and fentanyl 20 micrograms (total volume of solution 2.2 ml) was done. Control group: In a classic sitting position, spinal anesthesia with Quinke needle No. 25 from the inter-vertebral space L2-3 or L3-4 in the midline approach with bupivacaine 0.5% and fentanyl 20 micrograms (total volume of solution 2.2 ml) was done.

Main outcome variables
Spinal needle redirection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110712007013N28**
Registration date: **2020-11-07, 1399/08/17**
Registration timing: **retrospective**

Last update: **2020-11-07, 1399/08/17**
Update count: **0**

Registration date
2020-11-07, 1399/08/17

Registrant information

Name
Simin Atashkhoei
Name of organization / entity
Tabriz University of Medical Siences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2019-12-22, 1398/10/01

Actual recruitment end date
2020-03-19, 1398/12/29

Trial completion date
2020-03-19, 1398/12/29

Scientific title
Use of squatting position for facilitating of spinal block performance in patients undergoing cesarean

Public title
Squatting for facilitating of spinal block performance

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA class I or II Single term pregnancy Body mass index under 35 kg/m2 Candidate for elective cesarean section

Exclusion criteria:
Conscious dissatisfaction to enter the study Candidate for emergency cesarean section History of spinal surgery or spinal deformity including scoliosis, kyphosis and lordosis Contraindications to spinal anesthesia

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be using sealed envelopes, of which 120 envelopes will be selected in total and will be divided into two groups of 60, including groups A and B. Envelopes will be selected by the operating room nurse who is blind to the study groups. Group A will be the intervention group, group B will be the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study data were performed by a student and a respected midwife specialist unaware of the study. Spinal block and patients were monitored by an anesthesiologist and an anesthesia resident.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Vice chancellor for research, Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah Square

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2019-02-25, 1397/12/06

Ethics committee reference number
IR.TBZMED.REC.1397.1007

Health conditions studied

1

Description of health condition studied
Facilitating of Spinal Block Performance

ICD-10 code
O74.6

ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Spinal needle redirection

Timepoint
When doing spinal block

Method of measurement
Number of spinal needle redirection

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In a squatting position, spinal anesthesia with Quinke needle No. 25 from the inter-vertebral space L2-3 or L3-4 in the midline approach with bupivacaine 0.5% and fentanyl 20 micrograms (total volume of solution 2.2 ml) was done.

Category
Treatment - Other

2

Description
Control group: In a classic sitting position, spinal anesthesia with Quinke needle No. 25 from the inter-vertebral space L2-3 or L3-4 in the midline approach with

bupivacaine 0.5% and fentanyl 20 micrograms (total volume of solution 2.2 ml) was done.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Operation Room and Cesarean setting, Al Zahra Hospital,Tabriz University of Medical Sciences

Full name of responsible person
Dr. Simin Atashkhoei

Street address
Al Zahra hospital, Artesh Jonoubi Ave, Operating room, Dr. Simin Atashkhoyi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Ata Mahmoudpour

Street address
Vice chancellor for research, Tabriz University of medical sceinces, Daneshgah square

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Simin Atashkhoyi

Position
Associate Professor, Specialist in Anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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Position
Associate Professor, Specialist in Anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Sajjad Pourasghary

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

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

The request will be sent by email to person responsible for scientific or public inquiries.

Comments