

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of changing the position on shoulder pain after cesarean section under spinal anesthesia

Protocol summary

Study aim

The aim of this study was to evaluate shoulder pain after changing Trendelenberg position or head position with angle of 30 degrees at the time of peritoneum.

Design

The present study is a simple-blind, randomized, double-blind, placebo-controlled study with 35 patients in each group and phase 3.

Settings and conduct

The present study is a double-blind study in which patients and statistical analysts are not informed about the type of intervention.

Participants/Inclusion and exclusion criteria

All mothers who are candidates for elective cesarean section in term pregnancy have the following conditions, including non-urgent maternal and fetal reasons.

Pregnancy between 42-37 weeks and no spinal indications such as spinal cord infection. In maintaining the proper position .. Existence of neurological and neurological disorders. Maternal dissatisfaction with performing spinal. Coagulation abnormalities

Intervention groups

In the intervention group, the Trendelenberg position or downward shift of 30 degrees at the time of peritoneal closure.

Main outcome variables

shoulder pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190826044617N1**

Registration date: **2019-09-16, 1398/06/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-16, 1398/06/25**

Update count: **0**

Registration date

2019-09-16, 1398/06/25

Registrant information

Name

Parya Parvin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5209

Email address

parvinp951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-17, 1398/01/28

Expected recruitment end date

2020-04-16, 1399/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of changing the position on shoulder pain after cesarean section under spinal anesthesia

Public title

The effect of changing the position on shoulder pain after cesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All mothers were candidates for elective cesarean

section at term pregnancy Gestational age between 37-42 weeks

Exclusion criteria:

Spin Indicator counter Sensitivity to local anesthetic drugs Maternal inability to maintain proper position Presence of neurological disorders

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: 35

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is simple and the randomization unit is individualized, the position of patients is placed in a sealed envelopes and we assign one envelope to each patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data was sent in form of two Group (A and B) to the person responsible for data analysis and analyzer wasn't not aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Anesthesiology Department, Ahmadabad Ave, Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2019-04-17, 1398/01/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.016

Health conditions studied

1

Description of health condition studied

Other complications of spinal and epidural anaesthesia during labour and delivery

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description

Shoulder Pain

Timepoint

after intervention

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Trendelenberg position or downward shift of 30 degrees at the time of peritoneal closure.

Category

Prevention

2

Description

Control group: No change in patient position. (Without placebo)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Operations Room of Imam Reza (AS) and Vafaem (AS) Hospital in Mashhad

Full name of responsible person

Parya Parvin

Street address

Ahmadabad Ave, Ghaem Hospital and Imam Reza Hospital

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parvinp951@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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91375 345

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ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Parya Parvin

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

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

pdf of article

When the data will become available and for how long

after publication

To whom data/document is available

researchers

Under which criteria data/document could be used

sent an email

From where data/document is obtainable

sent an email

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

sent an email

Comments