Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of the patient's Trendelenburg position along with high volume ventilation and placement of long gas in the abdominal cavity on shoulder tip pain after cesarean section

Protocol summary

Study aim
Determining the effect of the patient's Trendelenburg position along with high volume ventilation and placement of long gas in the abdominal cavity on the occurrence of shoulder tip pain after cesarean section.

Design
A controlled, parallel-group, randomized, phase 2 clinical trial on 100 patients. The randomization method is a simple randomization method. The unit of randomization is individual.

Settings and conduct
This study will be conducted in Imam Reza Hospital of Mashhad and includes patients referred for cesarean section. In the intervention group, in the case of spinal anesthesia, the patients will be placed in the Trendelenburg position and long gauze will be placed on both sides of the uterus. In the control group, in the case of spinal anesthesia, they will be placed in a flat and horizontal position. Then, in both groups, 24 hours later, shoulder pain will be measured with VAS scoring criteria.No blinding was done.

Participants/Inclusion and exclusion criteria
The study inclusion criteria include all patients who are candidates for elective cesarean section. Exclusion criteria include patients not agreeing to participate in the study or causing any surgical or obstetric complications during cesarean surgery for the mother and baby.

Intervention groups
In the intervention group, in the case of spinal anesthesia, the patients will be placed in the Trendelenburg position, and long gauze will be placed on both sides of the uterus, and in the case of general anesthesia, ventilation with a higher volume will be used. became. In the control group, in the case of spinal anesthesia, they will be placed in a flat and horizontal position, and in the case of general anesthesia, they will receive medium-volume ventilation.

Main outcome variables
Shoulder pain after caesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231025059861N1**
Registration date: **2023-11-18, 1402/08/27**
Registration timing: **prospective**

Last update: **2023-11-18, 1402/08/27**
Update count: **0**

Registration date
2023-11-18, 1402/08/27

Registrant information

Name
Alireza Mortazavipasand
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
2023-11-21, 1402/08/30

Expected recruitment end date
2024-06-20, 1403/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the patient's Trendelenburg position along with high volume ventilation and placement of long gas in the abdominal cavity on shoulder tip pain after cesarean section

Public title

Investigating Trendelenburg position and high volume ventilation on shoulder pain after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Elective caesarean section candidates obtaining informed consent

Exclusion criteria:

Presence of chronic shoulder or upper limb pain History of any fracture in the shoulder joints

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is a simple randomization method. The unit of randomization is individual. Using the table of random numbers, patients are randomly divided into two groups: The experimental group and the control group. Even numbers are considered for the experimental group and odd numbers are for the control group. Random allocation is done by the researcher .

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 Mashhad University of Medical Sciences

Street address

No. 66, 24 Ave.motahhari Blvd

City

mashhad

Province

Razavi Khorasan

Postal code

7135574133

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.MUMS.IRH.REC.1401.065

Health conditions studied

1

Description of health condition studied

Shoulder pain in caesarean section patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Shoulder pain after caesarean section

Timepoint

24 hours after patients leave the recovery room and enter the ward

Method of measurement

The pain intensity will be measured based on the visual pain criterion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: including the patient's Trendelenburg position during cesarean section and with high volume ventilation and placement of long gas in the abdominal cavity

Category

Treatment - Devices

2

Description

Control group: Patients who were not placed in the Trendelenburg position during cesarean section and are in a flat position.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital
Full name of responsible person
Seyed Alireza Mortazavipasand
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Ebne Sina St
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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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
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
Seyed Alireza Mortazavipasand
Position
resident
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available