

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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. 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 cesarean 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2585

##### Email address

mortazavipasanda991@mums.ac.ir

##### 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

**Street address**

Ebne Sina St

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

91379133169

**Phone**

+98 51 3854 3031

**Email**

mortazavipasandA991@mums.ac.ir

## 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

**City**

mashhad

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Razavi Khorasan

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**Phone**

+98 51 3854 3031

**Email**

vcresraech@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**

Seyed Alireza Mortazavipasand

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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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