

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of head up position on severity of shoulder pain during and after cesarean section under spinal anesthesia

Protocol summary

Study aim

Determining the effect of head-up position on shoulder pain during and after elective caesarean section surgery under spinal anesthesia Comparison of the intensity of shoulder pain in supine and head-up positions during elective caesarean section surgery under spinal anesthesia in: 1. During operation 2. During recovery 3. 12 hours after the operation 4. 24 hours after the operation 5. 48 hours after the operation

Design

Clinical trial with two control and intervention groups, with parallel groups, one blind strain, with gradual random sampling, without drug intervention on 116 patients. The rand function of Excel software was used for randomization.

Settings and conduct

the effect of the head-up position on the severity of shoulder pain during and after surgery in elective caesarean section patients at Shahidan Mobini Hospital in Sabzevar. After the birth of the baby until the end of the recovery period, the patient is placed in one of two control or intervention groups and without blinding

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective Cesarean section with: Gestational age more than 36 weeks 18-45 years old Weight between 60-90 kg Exclusion criteria: History of seizures, Drug abuse, fracture or dislocation of shoulder joints and chronic pain in this area, chronic shoulder or upper limb pain, mental illness suffering from cardiovascular disease, blood pressure and Preeclampsia Contraindications for spinal anesthesia

Intervention groups

Head up position group (intervention): Placement in a 30 degree head up position, after the birth of the baby until the end of the recovery time. Supine group (control): Placement in supine position ,after the birth of the baby until the end of the recovery time

Main outcome variables

Shoulder pain, pain onset time, side of shoulder pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230816059160N1**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **prospective**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

Registration date

2023-09-25, 1402/07/03

Registrant information

Name

Zahra Izi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4466 7613

Email address

izizahraizi56@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of head up position on severity of shoulder pain during and after cesarean section under spinal anesthesia		Tawheed Shahr Blvd., above the Tomb of Anonymous Martyrs, University Campus Building, Ethics Committee	
Public title	Investigating the effect of position on the intensity of shoulder pain	City	Sabzevar
Purpose	Treatment	Province	Razavi Khorasan
Inclusion/Exclusion criteria		Postal code	9617913112
Inclusion criteria:	All elective caesarean section patients with a gestational age greater than 36 weeks All elective caesarean section patients aged 18-45 years All elective caesarean section patients weighing between 60-90 kg	Approval date	2023-07-19, 1402/04/28
Exclusion criteria:	History of seizures Drug abuse A history of fracture or dislocation of shoulder joints and chronic pain in this area History of chronic shoulder or upper limb pain Having a history of mental illness Suffering from cardiovascular disease Suffering from hypertension and preeclampsia Prohibition of spinal anesthesia	Ethics committee reference number	IR.MEDSAB.REC.1402.046
Age	From 18 years old to 45 years old	Health conditions studied	
Gender	Female	1	
Phase	N/A	Description of health condition studied	
Groups that have been masked	No information	Shoulder pain during and after cesarean section	
Sample size	Target sample size: 116	ICD-10 code	
Randomization (investigator's opinion)	Randomized	O60-O75	
Randomization description	This research is a probability sampling method. The samples are selected by gradual random sampling method after confirming that they meet the entry criteria and do not have the non-entry criteria. The samples are placed one by one in one of the test and control groups.	ICD-10 code description	
Blinding (investigator's opinion)	Not blinded	Complications of labour and delivery	
Blinding description		Primary outcomes	
Placebo	Not used	1	
Assignment	Parallel	Description	
Other design features		measuring of shoulder pain intensity with the Numeric Pain Rating Scale (NPRS)	
Secondary Ids		Timepoint	
empty		During cesarean section, during recovery, 12, 24 and 48 hours after the operation	
Ethics committees		Method of measurement	
1		The Numeric Pain Rating Scale (NPRS)	
Ethics committee		Secondary outcomes	
Name of ethics committee		empty	
Ethics committee of Sabzevar University of Medical Sciences		Intervention groups	
Street address		1	
		Description	
		Intervention group:In this group, the effect of position on shoulder pain in elective caesarean section patients under spinal anesthesia is investigated.After the birth of the baby until the end of the recovery, patients is placed in a 30 degree head-up position, and then the shoulder pain is measured from during the operation untill 48 hours after the operation in these times: during operation, during recovery, 12, 24 and 48 hours after operation.and then compared with the control group	
		Category	
		Treatment - Other	
		2	
		Description	

Control group: In this group of patients, they do not receive any treatment intervention. The patients are placed in a supine position after the birth of the baby until the end of recovery, and then the shoulder pain is measured from during the operation until 48 hours after the operation, in these times: during operation, during recovery, 12, 24 and 48 hours after operation, and then compared with the intervention group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahidan Mbini hospital

Full name of responsible person

Zahra Izi

Street address

North Kashfi Street, Mobini Hospital

City

Sabzevar

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9613856776

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Miri

Street address

Tawheed Shahr Blvd., above the tomb of anonymous martyrs, university campus building

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9613873136

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M.S@medsab.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Izi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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

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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