Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of early ambulation on post cesarean delivery pain and quality of recovery in the Mobini Sabzevar Hospital in 2024-2025

Protocol summary

Study aim
Determining effect of early ambulation on post cesarean delivery pain and quality of recovery

Design
The clinical trial has two control and intervention groups, double blind, Choice as available and division by permutation blocks and on 134 patients.

Settings and conduct
After coordinating with the supervisor of the surgery section of Mobini Sabzevar Hospital, collecting data in the surgery section shall be conducted . First, the patients after cesarean section are selected, based on entry criteria; Then the patients are divided into two groups that A will be placed in the intervention group which is the early ambulation method, then B will be placed in the control group which was the normal method of the department; C will be placed in the control group and D in the intervention group, and they will be placed in the control and intervention groups, respectively.

Participants/Inclusion and exclusion criteria
Entry criteria: post cesarean delivery patients; gestational age of 37 to 40 weeks; informed consent to participate in the study; sufficient consciousness to determine the intensity of pain; stable vital signs. Not-entry criteria: smoking and drug addiction; alcohol addiction; difficult pregnancy; having movement disorders or defects in the lower limbs; having a clear mental disorder and severe mood-emotional disorder that prevents effective communication; suffering from chronic diseases such as liver problems and immune system deficiency; lumbar disc disease; performing cesarean section after failure of natural delivery; extreme malnutrition with BMI less than 18.5.

Intervention groups
Intervention group: ambulation with a time interval of 4 hours after the operation and at a distance of 5 meters if the patient can tolerate it. Control group: ambulation of patient normally, 8 hours after cesarean section.

Main outcome variables
Reduced pain; increased quality of recovery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240509061715N1**
Registration date: **2024-06-05, 1403/03/16**
Registration timing: **prospective**

Last update: **2024-06-05, 1403/03/16**
Update count: **0**
Registration date
2024-06-05, 1403/03/16

Registrant information
Name
Maryam Mohammadiani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 4422 4946
Email address
mryam.mh76@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-06-21, 1403/04/01
Expected recruitment end date
2024-10-22, 1403/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of early ambulation on post cesarean delivery pain and quality of recovery in the Mobini Sabzevar Hospital in 2024-2025

Public title
The effect of early ambulation on post cesarean delivery pain and quality of recovery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Post cesarean delivery patients Gestational age of 37 to 40 weeks Informed consent to participate in the study Sufficient consciousness to determine the intensity of pain Stable vital signs

Exclusion criteria:
Smoking and drug addiction Alcohol addiction Difficult pregnancy Having movement disorders or defects in the lower limbs Having a clear mental disorder and severe mood-emotional disorder that prevents effective communication Suffering from chronic diseases such as liver problems and immune system deficiency Lumbar disc disease Performing cesarean section after failure of natural delivery Extreme malnutrition with BMI less than 18.5

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **134**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Not informing the outcome evaluator about the patient's membership in the control or intervention group Not informing the data analyst about the patient's membership in the control or intervention group

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Sabzevar ,Nuclear Martyrs Blvd ,Ethics commitee of Sabzevar University of Medical Sciences.

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Approval date
2024-04-17, 1403/01/29

Ethics committee reference number
IR.MEDSAB.REC.1403.002

Health conditions studied

1

Description of health condition studied
Cesarean delivery

ICD-10 code
O82.9

ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

Description
Pain

Timepoint
Before and immediately after the intervention, 12, and 18 hours after the operation

Method of measurement
Numerical rating pain scale

Secondary outcomes

1

Description
Quality of recovery

Timepoint
24 and 48 hours after the operation

Method of measurement
QOR15 scale

Intervention groups

1

Description

Intervention group: Early ambulation after cesarean surgery with an interval of 4 hours after surgery

Category

Treatment - Other

2

Description

Control group: Ambulation after cesarean surgery with an interval of 8 hours after surgery, as routine of the department

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobini Sabzevar Hospital

Full name of responsible person

Hasan Khalili

Street address

Hospital Mobini, Kashefi Ave.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856799

Phone

+98 51 4423 8100

Email

mh.lib@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Sabzevar University of Medical Sciences

Full name of responsible person

Kazem Hasan pour

Street address

Sabzevar, Nuclear Martyrs Blv, Sabzevar University Of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 8101

Email

drhassanpour@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Department of 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

Hasan Khalili

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Sabzevar, Davarzani 4 Ave, No 4

City

Sabzevar

Province

Razavi Khorasan

Postal code

9619614684

Phone

+98 51 4464 2383

Email

khalili894@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Maryam Mohammadiani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Sabzevar, Nuclear Martyrs Blvd, Sabzevar University of Medical Sciences.

City

Sabzevar

Province
Razavi Khorasan
Postal code
9619614493
Phone
+98 51 4422 4946
Email
mryam.mh76@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Maryam Mohammadiani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Sabzevar, Nuclear Martyrs Blvd, Sabzevar University of Medical Sciences.
City
Sabzevar
Province
Razavi Khorasan
Postal code
9619614493
Phone
+98 51 4422 4946
Email
mryam.mh76@gmail.com

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
Coordination with the relevant instructor in this regard has not been done yet.
When the data will become available and for how long
Coordination with the relevant instructor in this regard has not been done yet.
To whom data/document is available
Coordination with the relevant instructor in this regard has not been done yet.
Under which criteria data/document could be used
Coordination with the relevant instructor in this regard has not been done yet.
From where data/document is obtainable
Coordination with the relevant instructor in this regard has not been done yet.
What processes are involved for a request to access data/document
Coordination with the relevant instructor in this regard has not been done yet.
Comments