Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of Vitamin D and Vitamin E on the severity of postpartum pain

Protocol summary

Study aim
Determining the effect of vitamin E and vitamin D on the severity of postpartum painin women referred to Shahidan Mobini Hospital affiliated to Sabzevar University of Medical Sciences in 1401

Design
The clinical trial has a parallel control group, unblinded, randomized, on 100 mothers, the method of randomization: based on the days of the week, they will be divided into two intervention groups (even days) and a control group (odd days).

Settings and conduct
The study was conducted by the researcher using the selection of patients based on the provided guide in Shahidan Mobini Hospital affiliated to Sabzevar University of Medical Sciences.

Participants/Inclusion and exclusion criteria
18-35 years; Natural birth and first or second birth; Gestation age 37-42 weeks; Breastfeeding mother; Spontaneous placental discharge; So moderate to severe pain; Absence of grade 3 or 4 perineal tear; No epidural or spinal anesthesia Not using narcotic drugs before or during childbirth; No chronic diseases; No history of abdominal and pelvic surgery Absence of symptoms and history of D3 deficiency.

Intervention groups
In the intervention group, 8 pieces of vitamin E with a dose of 100 mg and 8 pieces of vitamin D with a dose of 400 mg will be provided to the samples. No intervention will be done in the control group. First, 2 hours after delivery, the intensity of postpartum pain will be measured with a McGill ruler. People with grades 4 and above will be selected.In both groups, the severity will be measured and recorded once 2 hours after delivery and before taking the pills and eight times after taking the medicine and if the pain is not relieved one hour after each intervention, a 250 mg dose of mefenamic acid will be given

Main outcome variables
Improvement of postpartum pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220313054270N1**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-01, 1401/08/10**
Update count: **0**

Registration date
2022-11-01, 1401/08/10

Registrant information

Name
mina ghalenovi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4422 6958

Email address
minaghalenovi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-11, 1401/07/19

Expected recruitment end date
2022-12-10, 1401/09/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Vitamin D and Vitamin E on the severity of

postpartum pain

Public title
The effect of Vitamin D and Vitamin E on the severity of postpartum pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The mother must be literate. The age of the mother should be between 18-35 years. Their delivery is natural and the first or second delivery. Pregnancy age is between 42-37 weeks. The mother is breastfeeding. The exit of the placenta and the curtains is done spontaneously. The mother has moderate to severe back pain.
Exclusion criteria:
The mother has not suffered a grade 3 or 4 perineal rupture. Epidural or spinal anesthesia is not used. During or before delivery, the drug has not been used to relieve pain, or 4 hours or more have passed since its us The mother should not be addicted to drugs. The mother does not have known chronic diseases (hypertension, diabetes, heart disease, infectious disease, lung disease, asthma) The mother has no history of abdominal and pelvic surgery The mother should not have symptoms of vitamin D deficiency (including bone and muscle pain, headache, and constant fatigue The patient has no history of vitamin D3 deficiency.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **43**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the days of the week, the research units will be divided into two groups A (intervention group) (Saturdays, Mondays, Wednesdays) and group B (control groups) (Sundays, Tuesdays, Thursdays).
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 Sabzevar University of Medical Sciences
Street address
Nuclear Martyrs Ave, Sabzevar University of Medical Sciences
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Approval date
2021-11-20, 1400/08/29
Ethics committee reference number
IR.MEDSAB.REC.1400.111

Health conditions studied

1

Description of health condition studied
postpartum pain
ICD-10 code
Z39.2
ICD-10 code description
Encounter for routine postpartum follow-up

Primary outcomes

1

Description
Severity of postpartum pain
Timepoint
2 hours after delivery and then every 6 hours up to eight times
Method of measurement
Through the McGill pain scale (to reach less than 4 after the intervention)

Secondary outcomes

1

Description
The amount of painkillers used
Timepoint
2 hours after delivery and then every 6 hours, the consumption of painkillers is checked
Method of measurement
patient file

2

Description
The amount of pain
Timepoint
2 hours after delivery and then every 6 hours up to 8

times

Method of measurement

Via McGill ruler

Intervention groups

1

Description

Intervention group: each person receives a packet containing 8 vitamin E with a dose of 100 mg and 8 vitamin D with a dose of 400 mg. and every 6 hours, they take one vitamin D and one vitamin E, and after every 6 hours, for 8 times. the pain level is measured by the McGill ruler.

Category

Treatment - Drugs

2

Description

Control group: It does not receive any interference. Routine hospital care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahidan Mobini Hospital affiliated to Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh Nodeh

Street address

North Kashfi Ave.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856776

Phone

+98 51 4423 8102

Email

Mobini.H@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Hosein Saghi

Street address

Nuclear Martyrs Ave, Sabzevar University of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 8101

Email

vc.Research@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

Mina Ghalenovi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Nuclear Martyrs Ave, Sabzevar University of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613943491

Phone

+98 51 4422 6958

Email

Minaghalenovi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mina Ghalenovi

Position
Coach

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Nuclear Martyrs Ave, Sabzevar University of Medical Sciences

City
Sabzevar

Province
Razavi Khorasan

Postal code
9613943491

Phone
+98 51 4422 6958

Email
Minaghalenovi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

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Mina Ghalenovi

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Minaghalenovi@yahoo.com

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
After the publication of the article, confidential information such as patient and hospital details will be removed and other information will be provided to the researchers

When the data will become available and for how long
After the publication of the article

To whom data/document is available
Medical experts

Under which criteria data/document could be used
Medical professionals can access the data for research purposes

From where data/document is obtainable
Refer to the email of the responsible author.

What processes are involved for a request to access data/document
Official and academic email to the corresponding author

Comments