

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 pain in 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 use. 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

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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

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North Kashfi Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Hosein Saghi

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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

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Person responsible for updating data

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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