Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Investigating the effect of Valeriana Officinalis Capsule on postpartum pain

Protocol summary

Study aim
Determining the effect of valerian capsules on the severity of postpartum pain

Design
Randomized controlled clinical trial with parallel groups, triple blind, phase 3 on 70 primiparous women. Randomization will be done using Excel software with the function of random numbers.

Settings and conduct
This study will be conducted in the field of postpartum care in the Mahdieh Hospital, Tehran.The sample size includes 70 primiporous women who will be randomly divided into two groups. For all research units, the questionnaire of personal and demographic information is completed and the checklist for assessing the severity of back pain is completed before the start of intervention. The study is triple-blinded (the samples, researchers and analysts are unaware of which person is receiving the drug or the placebo).After the intervention, the two groups will be evaluated and compared to the severity of back pain

Participants/Inclusion and exclusion criteria
Inclusion criteria:Iranian women, married, vaginal delivery, baby weight between 2500 and 4000 grams, women with moderate to severe back pain, speaking Persian, primiparous, age between 18 and 35 years old. Exclusion criteria: occurrence of complications after childbirth, including bleeding, fever and high blood pressure 90/14

Intervention groups
Intervention group:2 hours after delivery, every 8 hours for 24 hours, one valeriana capsule containing 500 mg of drug powder is given. Control group:2 hours after delivery,a placebo capsule containing 500 mg of starch is given every 8 hours for 24 hours. This capsule will be prepared in the school of Pharmacy of Shahid Beheshti.

Main outcome variables
Severity of postpartum pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100130003226N21**
Registration date: **2024-01-03, 1402/10/13**
Registration timing: **prospective**

Last update: **2024-01-03, 1402/10/13**
Update count: **0**

Registration date
2024-01-03, 1402/10/13

Registrant information

Name
Mahrokh Dolatian

Name of organization / entity
Shahid Beheshti University of Medical Scenices

Country
Iran (Islamic Republic of)

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+98 21 8820 2512

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Valeriana Officinalis Capsule on postpartum pain

Public title
Effect of valerian capsule on postpartum pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian Married Have Vaginal delivery The baby's weight should be between 2500 and 4000 gr Have moderate to sever postpartum pain Speak Persian Nulliparous Aged 18 - 35 years

Exclusion criteria:
Complication after delivery such as vaginal bleeding Fever Taking another painkillers more than one dose per day blood pressure more than 140/90

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment to intervention and control groups: The function of random numbers will be used to randomize and assign people to groups. Randomization will be done using Excel software and the list of random numbers will be the total number of samples, which will be recorded in front of each drug code number A or B. Before starting the study, the capsules will be placed in similar envelopes by the drug consultant, and code A or B will be recorded on each envelope. 4 capsules will be placed in each envelope.There are 4 medicine capsules in one envelope and 4 placebo capsules in the next envelope. after the start of the study, based on the list of random numbers and specified groups, the envelopes of medicines will be provided by the researcher to the research units in the order of entry into the study. Mefenamic acid routine treatment will be given to both groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
When preparing medicine and placebo, the pharmacist gives a code of one or two to their cans, and the code will remain hidden for the researcher, research unit and data analyst until the end of the analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Pharmacy, Nursing and Midwifery Faculties of Shahid Beheshti University of Medic

Street address
No.1,Ethics Committee of Pharmacy, Nursing and Midwifery Faculties of Shahid Beheshti University of Medical Sciences,In front of Shahid Rajaei Heart Hospital,Hashemi Rafsanjani Blvd,Valiasr Ave. Tehran

City
Tehran

Province
Tehran

Postal code
1996835119

Approval date
2023-03-07, 1401/12/16

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.289

Health conditions studied

1

Description of health condition studied
postpartum pain

ICD-10 code
R10.2

ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Severity of postpartum pain

Timepoint
Before the intervention and one hour after

Method of measurement
MacGill Pain Ruler

Secondary outcomes

1

Description

Side effects of the drug

Timepoint

after intervention

Method of measurement

side effect questionnaire

Intervention groups

1

Description

Intervention group: 2 hours after delivery, every 8 hours for 24 hours, a Valerian capsule containing 500 mg of its powder is given, and one hour after each intervention, if the pain does not improve, a 250 mg Mefenamic acid capsule is given. This capsule will produce at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: 2 hours after delivery, every 8 hours for 24 hours, a placebo capsule containing 500 mg of starch powder is given, and one hour after each intervention, if the pain does not improve, a 250 mg Mefenamic acid capsule is given. This capsule will produce at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Atena Mohammady Rouzbahani-Zohreh Jafari

Street address

Shahid Rajab Nia St., Shihgar Khane Alley, Shoush Square, Fedaiyan Islam St., Tehran

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mahdiyeh_hospital@sbmu.ac.ir

Web page address

https://mmc.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

Street address

University Building No. 2 of ShahidBeheshti University of Medical Sciences, Parvaneh Str., Yemeni Ave, Shahid Chamran Highway

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Zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Mahrokh Dolatian

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Gynecology Department, In front of Shaheed Rajaee Heart Hospital, The intersection of Niayesh, Vali asr street, Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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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