Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of (Cuminum cyminum,Foeniculum and Anethum graveolens dhi) capsule on a postpartum pain

Protocol summary

Study aim

Determining the effect of the capsule (cumin, dill, and fennel) on postpartum pain

Design

The clinical trial has control and intervention group, three-way blind, randomized, on 100 patients by Excel software

Settings and conduct

The intervention is performed in the postpartum ward of Shohadae 15 Khordad Hospital in Varamin, in two groups. According to the ward's regulation, women receive a 250 mg mefenamic acid capsule. In addition to the mefenamic acid capsule, one capsule (cumin, dill, and dill)/placebo will be given. For blinding, the intervention is performed by a researcher (midwife with similar work experience).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal vaginal delivery, Gestational age 37-42 weeks, Live child,Weight of baby born between 2500-4000 grams, Moderate or severe postpartum pain. Exclusion criteria: Severe bleeding, grade 3 or 4 of perineal rupture, History of allergies to medicinal plants

Intervention groups

Herbs (cumin, dill, and fennel) will be purchased and after approving the identification, by soaking in ethanol alcohol at 96 degrees method, they will be extracted. Then the plant extraction (cumin, dill, and fennel) will be mixed with corn starch and filled in 500 mg capsules. Each capsule contains 300 mg prepared extraction from 100 mg of each plant extract .The placebo capsule contains dry bread and will be prescribed in a similar dose and capsule in the control group. These capsules are prescribed every 8 hours, 2 to 24 hours after normal delivery for mothers who meet the inclusion criteria and are categorized in the Intervention and control groups.

Main outcome variables

Severity and duration, and time of postpartum pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211130053228N1**
Registration date: **2022-03-05, 1400/12/14**
Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**
Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

Masoome Tajik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3626 4863

Email address

masoome.tajik@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of (Cuminum cyminum,Foeniculum and Anethum graveolens dhi) capsule on a postpartum pain

Public title

The effect of (Cuminum cyminum,Foeniculum and Anethum graveolens dhi) capsule on a postpartum pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

normal vaginal delivery. The gestational age between 37-42 weeks The live single neonate with cephalic presentation The birth weight 2500-4000 grams. moderate to severe postpartum pain based on Visual scale of pain The placental removal are is spontaneous.

Exclusion criteria:

Severe postpartum hemorrhage. Prolonged delivery and use vacium. Analgesia and epidural anesthesia, spinal anesthesia during labor Addiction History of systemic diseases Grade 3 or 4 perineal laceration History of allergies to medicinal plants

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment method using Excel software, in one of two groups of intervention and control

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding, the intervention is performed by the researcher's colleague (midwife with similar work experience) and the researcher is not aware of the intervention and control groups. The same and with codes A and B will be prepared and coded by Pharmaco Gnosist consultant. The researcher will not know the codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Schools of Pharmacy, Nursing and Midwifery - Shahid Beheshti University of Medical Sciences

Street address

Unit 17،Persepolis building،in front of Madani clinic، Shahid Rajaei Street

City

Varamin

Province

Tehran

Postal code

33718-38975

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.212

Health conditions studied

1

Description of health condition studied

postpartum pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The severity of postpartum pain

Timepoint

1-2-3-4-5-6-12-18-24 hours after delivery

Method of measurement

Pain ruler

2

Description

Duration of pain after delivery

Timepoint

1-2-3-4-5-6-12-18-24 hours after delivery

Method of measurement

Timer

3

Description

Time of pain relief after delivery

Timepoint

1-2-3-4-5-6-12-18-24 hours after delivery

Method of measurement

Timer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Herbs (cumin, dill, and fennel) will be purchased and after approving the identification, by soaking in ethanol alcohol at 96 degrees method, they will be extracted. Then the plant extraction (cumin, dill, and fennel) will be mixed with corn starch and filled in 500 mg capsules. Each capsule contains 300 mg prepared extraction from 100 mg of each plant extract. This capsule is prescribed every 8 hours, 2 to 24 hours after normal delivery for mothers who meet the inclusion criteria. The mother will also given mefenamic acid capsule.

Category
Treatment - Drugs

2

Description
Control group: The placebo capsule will be prepared by the Pharmacognosy Research Center of Shahid Beheshti University of Medical Sciences and will be prescribed in the identical dose and capsule in the control group. mother will also given mefenamic acid capsule.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
15 Khordad shohadan Varamin Hospital

Full name of responsible person
Masoome Tajik

Street address
Entrance of Varamin city

City
Varamin

Province
Tehran

Postal code
3371461916

Phone
+98 21 3502 3337

Email
masoometajik5@gmail.com

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
Shahid Chamran Highway, Yemen St. - Shahid Arabi St. next to Ayatollah Taleghani Hospital

City
Tehran

Province
Tehran

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1985717443

Phone
+98 21 23871

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info@sbmu.ac.ir

Web page address

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
Social Security Organization

Full name of responsible person
Masoome Tajik

Position
Midwife

Latest degree
Master

Other areas of specialty/work
Midwifery

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Entrance of Varamin city- Shohada15 Khordad Varamin Hospital

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massometajik5@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Mahboubeh Ahmadi Dolabi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Vali Asr St., Niayesh Intersection, in front of Shahid Rajaei Heart Hospital

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Person responsible for updating data

Contact

Name of organization / entity
Social Security Organization

Full name of responsible person
Masoome Tajik

Position
Midwife

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Entrance of Varamin city- Shohada15 Khordad Varamin Hospital

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Varamin

Province
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Postal code
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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable