Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparing of the effect of" Ginger-Lavender" capsule with" Mefenamic Acid" on postpartum pain

Protocol summary

Study aim
Considering the importance of postpartum pains reduction for better care and effective interaction between mother and baby after delivery, the aim of this study is to compare the effect of Ginger-Lavender capsule with Mefenamic Acid on postpartum pains in women referred to Valiasr Hospital in Fasa in 1400.

Design
Controlled clinical trial work, with parallel groups, triple-blind, randomized, phase 3 on 94 women, Excel software for randomization

Settings and conduct
After sampling from women referring to the maternity ward of Valiasr Hospital in Fasa based on the entry criteria, sampling will be done continuously and purposefully. The method of coding on pharmaceutical bags is used for blinding. Researcher, samples and statistics consultants are blind.

Participants/Inclusion and exclusion criteria
Entry criteria:15 to 44 years old; Minimum literacy; Vaginal delivery; 37 to 42 weeks of gestational age; Moderate to severe postpartum pain; No instrumental delievery; No 3rd and 4th degree rupture; No history of chronic/systemic diseases; No history of C-section surgery; No use of epidural/spinal anesthesia; No drug addiction; No history of allergies to herbal medicines; Successful breastfeeding; Singleton delivery and healthy baby; Have no complications of childbirth; 2nd delivery or more Exit criteria:Mother unwillingness; No pain relief with study drugs; Sensitivity to the drug; Use chemical and herbal analgesics other than studies; Suffers from postpartum complications during the intervention; Have a history of more than one delivery.

Intervention groups
2 hr after delivery, Pain intensity is recorded in two groups(Ginger-Lavender and Mefenamic Acid) by VAS, prior the intervention and one hour after. 300 mg capsules of "Ginger-Lavender" and 250 mg of "Mefenamic Acid" 4 times a day for one day after delivery. At the end, average pain will be evaluated.

Main outcome variables
Severity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200525047565N3**
Registration date: **2021-11-12, 1400/08/21**
Registration timing: **prospective**

Last update: **2021-11-12, 1400/08/21**
Update count: **0**

Registration date
2021-11-12, 1400/08/21

Registrant information

Name
Sharareh Jannesari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8820 2512

Email address
shararehjannesari@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the effect of" Ginger-Lavender" capsule with" Mefenamic Acid" on postpartum pain

Public title

Comparing of the effect of" Ginger-Lavender" capsule with" Mefenamic Acid" on postpartum pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be 15 to 44 years old Have minimum literacy Have vaginal delivery Be in 37 to 42 weeks of gestational age Complain of moderate to severe postpartum pain Do not have the delivery with the help of tools Have no 3rd and 4th degree rupture No history of chronic or systemic diseases such as diabetes or high blood pressure Have no history of cesarean section and intra-abdominal surgery Do not use epidural and spinal anesthesia during labor Do not have any drug addiction Have no history of allergies to herbal medicines Successful breastfeeding has begun Have a singleton delivery and healthy baby Have no complications of childbirth such as bleeding, fever and high blood pressure Have a history of more than one delivery

Exclusion criteria:

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

First, sampling is selected based on the number of targets from the women referring to the maternity ward of Valiasr Hospital in Fasa. After introducing herself, the researcher will explain to the participants the goals and how to implement the research. Then, if they have the conditions to enter the study, they are divided into two groups of capsule users "Ginger - Lavender" and "Mefenamic Acid" by accidental assignment using Excel software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The blinding was done in such a way that the capsule containing Ginger-Lavender was prepared in exactly the same way as the Mefenamic Acid capsule and coded. Only the Pharmacogenesis Consultant is aware of its contents and codes, and the researcher and participants in the research and data analyzer are unaware of it. In this way, the study will be done in triple blind ways.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, School of Pharmacy, Nursing, Midwifery of Shahid Beheshti University

Street address

School of Nursing and Midwifery, Opposite to Rajaee Heart Hospital, Valiasr Street, Intersection of Niayesh Highway, Tehran. Iran.

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2021-10-16, 1400/07/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.167

Health conditions studied

1

Description of health condition studied

postpartum pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

severity of pain

Timepoint

2 hours after delivery, To be evaluated every 6 hours before and one hour after the intervention until 24 hours after delivery.

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: "Ginger-lavender" group of 300 mg capsules containing 250 mg of ginger and 50 mg of Lavender extract prepared in Shahid Beheshti School of Traditional Medicine 4 times a day (every 6 hours) from 2 hours after delivery. They will receive up to 24 hours. Basic pain (before the intervention) and then one hour after each intervention is measured with a visual analogue scale.
Category
Treatment - Drugs

2

Description
Control group: "Mefenamic Acid" group will receive 250 mg "Mefenamic Acid" capsules of Amin Company daily (one every 6 hours) from 2 hours after delivery until 24 hours later. Basic pain (before the intervention) and one hour after each intervention is measured with a visual analogue scale.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Nadereh Ashkan
Street address
Valiasr Hospital, Ibn Sina Square, Fasa, Fars
City
Fasa
Province
Fars
Postal code
7461686688
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+98 71 5333 4020
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Arabi St, Yemen St, next to Ayatollah Taleghani Hospital, Shahid Chamran Highway, Tehran
City
Tehran
Province
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Postal code
1983963113
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info@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
sharareh Jannesari
Position
Midwifery Instructor
Latest degree
Master
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery, in front of Rajaee Heart Hospital, Vali-Asr St, Intersection of Niyayesh Highway, tehran, Iran.
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sharareh Jannseari

Position
Midwifery Instructor

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Person responsible for updating data

Contact

Name of organization / entity
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+98 21 8865 5366

Email
Shararehjannesari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data remains confidential to the researcher at first.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
This research is to observe the effect of “Ginger-Lavender” Capsule to reduce postpartum after-pains

When the data will become available and for how long
After the article is published in the desired journal is available.

To whom data/document is available
Everyone who is interested in the article.

Under which criteria data/document could be used
To increase the quality of women's lives and to use more herbal medicine.

From where data/document is obtainable
Email the corresponding author.

What processes are involved for a request to access data/document
Explain the reasons for requesting an article in the email.

Comments