Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of capsule containing Pelargonium graveolens (Geranium) on postpartum blues in primiparous women

Protocol summary

Study aim
Determining the effect of capsule containing Pelargonium graveolens (Geranium) on postpartum blues in primiparous women.

Design
Randomized controlled clinical trial with parallel groups, three blind strains. Randomization will be done using Excel software with random number function.

Settings and conduct
The study will be conducted in the field of postpartum blues in health centers in Shahreza with a sample size of 100 primiparous women who will be randomly assigned to two groups. For all participants, the Stein questionnaire will be completed before the intervention and on days 10 and 14 after delivery (participants, researchers, and statistical analysts are blinded), and after the intervention, the two groups will be compared in terms of postpartum blues.

Participants/Inclusion and exclusion criteria
primiparous, be between 18 and 35 years old, gestational age of 37 to 42 weeks, alive and single fetus, have no history of mental disorders and severe stress, have no adverse pregnancy and delivery outcomes, have no history of experiencing unfortunate and stressful events, symptoms of postpartum blues(Stein questionnaire and a score higher than 8).The mother should not be willing to participate in the study, show symptoms of allergy to geranium.

Intervention groups
Intervention group: Mothers who refer to health centers for first postpartum care within 3-5 days after delivery will be prescribed a geranium capsule producted by Barij Company twice a day for 14 days. The Stein questionnaire will be completed before the intervention and on days 10 and 14 after delivery. Control group: Mothers who refer to health centers for first postpartum care within 3-5 days after delivery will be prescribed a placebo capsule twice a day for 14 days. The Stein questionnaire will be completed before the intervention and on days 10 and 14 after delivery.

Main outcome variables
Postpartum blues

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100130003226N27**
Registration date: **2026-07-22, 1405/04/31**
Registration timing: **prospective**

Last update: **2026-07-22, 1405/04/31**
Update count: **0**

Registration date
2026-07-22, 1405/04/31

Registrant information

Name
Mahrokh Dolatian

Name of organization / entity
Shahid Beheshti University of Medical Scenices

Country
Iran (Islamic Republic of)

Phone
+98 21 8820 2512

Email address
m_dolatian@sbmu.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15

Expected recruitment end date
2027-10-07, 1406/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of capsule containing Pelargonium graveolens (Geranium) on postpartum blues in primiparous women

Public title
The effect of capsule containing Pelargonium graveolens (Geranium) on postpartum blues
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being Primiparous woman. Aged 18 to 35 years. Being literate in reading and writing. Being Iranian. Gestational age between 37 to 42 weeks. Having alive and single fetus. Fetal weight between 2500 and 4000 gr. Live with her husband and her husband has no other wife. Do not have a history of mental disorders or severe stress. Do not use chemical medications (antidepressants, sedatives or sleeping pills such as fluoxetine, sertraline) at the same time. No smoking, alcohol and drugs. No history of two or more miscarriages. Do not suffer from adverse pregnancy and delivery outcomes including premature birth, instrumental delivery, birth of a baby with congenital abnormalities, preeclampsia, eclampsia, postpartum hemorrhage, infection, and breast problems. No history of experiencing unfortunate and stressful events (serious illness of herself or her spouse and child, death of a loved one, accident, severe family conflict, divorce, immigration, dismissal or unemployment of herself or her spouse, and bankruptcy). Having symptoms of postpartum blues. (According to the Stein questionnaire and obtaining a score higher than 8) No history of allergy to herbal medicines, according to the individual's statement.
Exclusion criteria:
The mother or baby may need to be hospitalized. Allergy to Geranium capsules. The individual may not be willing to participate in the study.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
It is available (simple) and goal based. In this way, all primiparous mothers who meet the conditions for entry into the study will be examined. Randomization will be done using Excel software; the list of random numbers will be the total number of samples, which will be recorded in front of each capsule code number A or B. Before the start of the study, the capsules will be placed in similar envelopes by the pharmacist consultant and the code A or B will be recorded on each envelope. 30 capsules will be placed in each envelope, and after the start of the study, based on the list of random numbers and the specified group in the order of entry into the study, the envelopes of capsules will be provided by the researcher to the research units.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Geranium capsules and placebo are coded by the pharmacist; Researchers, research units and statistical analysts will be unaware of their content.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University
Street address
School of Nursing and Gynecology Department ,In front of Shahid Rajaee Heart Hospital, The intersection of Niayesh, Vali Asr street, Tehran Town
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2026-07-20, 1405/04/29
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1405.121

Health conditions studied

1

Description of health condition studied
Postpartum blues
ICD-10 code
O90.6
ICD-10 code description
Postpartum mood disturbance

Primary outcomes

1

Description
Postpartum blues
Timepoint
Before intervention (days 3-5 after delivery), days 10 and 14 after delivery
Method of measurement
Stein questionnaire

Secondary outcomes

1

Description
Side effects of the drug
Timepoint
14th after delivery
Method of measurement
Drug side effects questionnaire

Intervention groups

1

Description
Intervention group: Mothers who refer to health centers for first postpartum care within 3 to 5 days after delivery will be prescribed the intervention capsule twice a day for 14 days and the Stein questionnaire will be completed before the intervention and on days 10 and 14 after delivery.
Category
Treatment - Drugs

2

Description
Control group: Mothers who refer to health centers for first postpartum care within 3 to 5 days after delivery will be prescribed the placebo capsule twice a day for 14 days and the Stein questionnaire will be completed before the intervention and on days 10 and 14 after delivery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Centers affiliated with Isfahan Medical Sciences
Full name of responsible person
Sabere Shirali
Street address
Shahreza, Modares Blvd., next to Shahreza Imamzadeh, Shahreza Healthcare Network
City
Shahreza
Province
Isfehan
Postal code
8619665491
Phone
+98 31 5322 3071
Email
webmaster@nm.mui.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 Bulding No.2 of Shahid Beheshti University of Medical Sciences, Parvaneh Str., Yemeni Ave.,Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2234 9981
Email
Zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti University of Medical Science
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

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Gynecology Department ,In front of Shahid Rajaee Heart Hospital, The intersection of Niayesh, Vali Asr street, Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

009888655366

Email

mhdolatian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mahrokh Dolatian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Gynecology Department ,In front of Shahid Rajaee Heart Hospital, The intersection of Niayesh, Vali Asr street, Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

mhdolatian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sabere Shirali

Position

Master student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Gynecology Department ,In front of Shahid Rajaee Heart Hospital, The intersection of Niayesh, Vali Asr street, Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 3566

Email

SabereShirali80@gmail.com

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