Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Preliminary Evaluation of the Efficacy of Pardihan Syrup (a Combination of Grape Syrup, Apple Extract, and Basil) in Managing Postpartum Depression (PPD): A Pilot Study

Protocol summary

Study aim

To evaluate the efficacy of Pardihan syrup (a combination of grape syrup, apple extract, and basil) in managing mild to moderate postpartum depression in women aged 18-40.

Design

A randomized, double-blind, parallel-group, placebo-controlled pilot study.

Settings and conduct

The sampling of this clinical trial will be conducted at Khalij Fars Hospital, Bushehr. After screening participants based on inclusion and exclusion criteria and obtaining written informed consent, individuals are assigned to either the intervention or control group using blocked randomization with allocation concealment. The study is conducted in a double-blind manner, meaning the participants, and the outcome assessors are all unaware. Blinding is maintained by using a placebo that is identical consistency to the active syrup. Weekly telephone follow-ups will monitor treatment adherence and any potential adverse events. Outcomes are assessed on Day 1 and 30.

Participants/Inclusion and exclusion criteria

Twenty women, aged 18-40, who are 2-12 weeks postpartum with a diagnosis of mild to moderate postpartum depression will be enrolled. Key exclusion criteria include the use of other antidepressants, known allergies to the syrup's components, or a history of other major psychiatric disorders.

Intervention groups

Participants will be randomized to one of two groups: the intervention group receiving Pardihan syrup or the control group receiving a matching placebo. The placebo, produced by the same manufacturer, is identical in all sensory characteristics (color, taste, smell) to ensure blinding integrity. The regimen is 10ml, administered three times daily for 30 consecutive days.

Main outcome variables

The primary outcome is the change in depression score from baseline to Day 30, measured by the PHQ-9. Secondary outcomes include changes in anxiety scores (BAI), sleep quality (PSQI), and mother-infant bonding (PIBI).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250605066071N1**
Registration date: **2025-08-14, 1404/05/23**
Registration timing: **retrospective**

Last update: **2025-08-14, 1404/05/23**
Update count: **0**

Registration date

2025-08-14, 1404/05/23

Registrant information

Name

Pooya Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-16, 1404/04/25

Expected recruitment end date

2025-07-27, 1404/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preliminary Evaluation of the Efficacy of Pardihan Syrup (a Combination of Grape Syrup, Apple Extract, and Basil) in Managing Postpartum Depression (PPD): A Pilot Study

Public title

Effectiveness of Pardihan Syrup in Managing Mild to Moderate Postpartum Depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1.Mothers with mild to moderate postpartum depression. 2.Mothers aged between 18 and 40 years, who are 2 to 12 weeks postpartum. 3. 4. 5. 6. Mothers aged between 18 and 40 years, who are 2 to 12 weeks postpartum. No use of antidepressant medications to manage the condition. Birth of a healthy infant.Mothers must have at least basic literacy (reading and writing skills). Pregnancy must have been low-risk. Maternal body mass index (BMI) must be less than or equal to 40 kg/m^2.

Exclusion criteria:

Mother's unwillingness to continue participating in the study to receive syrup for 2 consecutive days Sensitivity to Pardihan syrup A history of previous depression with an unrelated cause A history of taking antidepressants Women who suffer from other mental illnesses or take related medications having Diabetes having Polycystic ovary syndrome Failure to complete the course of taking interventions

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization will be used to allocate participants into groups. Given the small sample size of the study (20 participants), this method ensures that the number of participants remains balanced between the intervention and control groups at each stage of sampling. The allocation process is as follows: 1. Blocks of four participants (with six possible combinations such as AABB, ABAB, ABBA, BBAA, BABA, BAAB) will be generated by a third party who is not involved in the screening or enrollment of participants. 2. The allocation sequence based on the randomized blocks will be placed in sealed and numbered envelopes (allocation concealment). 3. After obtaining informed consent from each eligible participant, the envelopes will be opened in numerical order, and the participant will be assigned to the designated group (A: intervention or B: placebo)

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double-blind trial, meaning that participants, the treatment/research team, and outcome assessors are all unaware of the type of intervention each group receives. To ensure successful blinding, the pharmaceutical company Sanabel Darou has manufactured the placebo to be indistinguishable from the active syrup in all visible characteristics, including color, taste, smell, viscosity, and packaging. Bottles for both groups are labeled with a unique code, and only the allocation officer (the third party) is aware of the actual contents. The codes will remain undisclosed until the completion of the statistical analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bushehr University of Medical Sciences

Street address

Student Research Committee, Bushehr University of Medical Sciences, Bushehr, Rishehr St., Salman Farsi St., Pardis Complex

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2025-04-16, 1404/01/27

Ethics committee reference number

IR.BPUMS.REC.1404.062

Health conditions studied

1

Description of health condition studied

Postpartum depression, Anxiety

ICD-10 code

F53.0

ICD-10 code description

Postpartum depression, Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Depression score

Timepoint

Filling out the questionnaire will be done at the beginning of the study (before the intervention) and 30 days after the start of the study.

Method of measurement

Physical Health Questionnaire (PHQ)

Secondary outcomes

1

Description

Sleep quality

Timepoint

Filling out the questionnaire will be done at the beginning of the study (before the intervention) and 30 days after the start of the study.

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

intensity of anxiety

Timepoint

Filling out the questionnaire will be done at the beginning of the study (before the intervention) and 30 days after the start of the study.

Method of measurement

Beck Anxiety Inventory

3

Description

Mother-infant relationship quality

Timepoint

Filling out the questionnaire will be done at the beginning of the study (before the intervention) and 30 days after the start of the study.

Method of measurement

Parent-ChildBonding Instrument

Intervention groups

1

Description

The intervention group will receive Pardehan syrup at a dose of 10 cc (equivalent to one tablespoon), three times a day for 30 consecutive days.

Category

Treatment - Other

2

Description

The control group will receive the placebo syrup at the same dose of 10 cc (equivalent to one tablespoon), three times a day for 30 consecutive days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalij Fars hospital, Bushehr

Full name of responsible person

Seyed Mohammad Javad Mousavi

Street address

Persian Gulf Hospital Bushehr, Bushehr, Niayesh Blvd., Shohada Navecheh Paykan, Persian Gulf Hospital

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Sponsors / Funding sources

1

Sponsor

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Boushehr University of Medical Sciences

Full name of responsible person

Seyed Mohammad Hadi Emamat

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Grant name

Grant code / Reference number

2973

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

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Seyed Mohammad Javad Mousavi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data

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Other areas of specialty/work

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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

No - There is not 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

The shared materials will include the de-identified Individual Participant Data (IPD), the final Study Protocol, the Statistical Analysis Plan (SAP), and the corresponding Data Dictionary. The IPD dataset will encompass all variables collected for the primary and secondary outcomes, including but not limited to: baseline demographic characteristics, complete scores from the PHQ-9 questionnaire, quality of life and sleep assessments, and baseline hematological parameters. The Data Dictionary will be provided to ensure the full interpretability of the dataset by defining each variable, its unit of measurement, and coding scheme. All data will be fully anonymized to protect participant confidentiality.

When the data will become available and for how long

Access to the data and related documents will become available starting 1 year after the publication of the primary study results. This access will be guaranteed for a minimum period of 1 year from the start date to support scientific verification and secondary research.

To whom data/document is available

Access will be granted to qualified researchers affiliated with accredited academic, scientific, or non-commercial research institutions for the purpose of conducting verifiable scientific inquiry.

Under which criteria data/document could be used

The data or documentation provided is intended solely for legitimate research purposes. Use of this data must align with clearly defined scientific objectives, a sound research design, and adherence to ethical research principles. Applicants must be affiliated with an academic or research institution and are required to commit to using the data exclusively for the purpose stated in their request. Requesters must also provide assurance of their capacity to store the data securely in accordance with their institutional data protection policies. Sharing the data with third parties without prior written permission is strictly prohibited. Use of the data for commercial or promotional activities is strictly prohibited, unless explicitly authorized by the Principal Investigator of the original study. Any request for such use will be subject to a rigorous review based on the scientific, ethical, and public health merits of the proposal. Approval is granted solely at the discretion of the Principal Investigator, and if granted, will be governed by a separate, legally binding agreement that specifies the precise terms and conditions of use. In the event that the data is used in published articles or reports, appropriate citation of the data source is mandatory, and collaboration with the original research team must be acknowledged.

From where data/document is obtainable

Requests should be directed via email to the corresponding author (M.j.mousavi@bpums.ac.ir). Should this contact be unavailable, inquiries can be directed to the research office of Bushehr University of Medical Sciences.

What processes are involved for a request to access data/document

To request access to the data and associated documents, applicants must submit a formal request via email to the corresponding author. The request must include: 1. A concise research proposal (1-2 pages) detailing the scientific objectives, methodology, and the intended use of the data. 2. The applicant's institutional affiliation and contact information. 3. A signed statement confirming commitment to data confidentiality and secure storage. The Principal Investigator (PI) and research team reserve the right to request additional information or clarification regarding the proposal. All complete applications will be reviewed by the PI and research team. The review will assess the scientific merit, ethical soundness, and feasibility of the proposed research, ensuring it does not conflict with ongoing or planned analyses by the original team. The PI reserves the full right to approve or reject any request based on this review. The review process is expected to take 2 to 4 weeks, commencing from the date a complete application is received. The decision of the review team is final. If the request is approved, the applicant will be required to sign a formal Data Sharing Agreement (DSA) before access is granted. Following the execution of the DSA, data will be provided in a de-identified format and in a standard, non-proprietary file type (e.g., CSV).

Comments