Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Matricaria Chamonail on postpartum depression

Protocol summary

Study aim
Determining the effect of chamomile extract on postpartum depression
Design
Randomised, parallel group trial with blinded outcome assessment.
Settings and conduct
Women referring to health centers No.1 , NO.4, Modares and Farhangian of Dezful city who have the conditions to enter the study and have mild to moderate depression, enter the study. Individuals will be divided into two groups of 72 through random allocation. Each participant receives two capsules daily (placebo or chamomile extract 500mg) for 8 weeks. The trial is two-blind and the participant and the researcher do not know the type of treatment for each person. Beck Depression questionnaire will be completed at the beginning of treatment and at the end of treatment.
Participants/Inclusion and exclusion criteria
Women who have given birth will have mild to moderate depression
Intervention groups
Participants in each group received 1000 mg (twice a day) for 8 weeks of medication (placebo or extract). Beck depression questionnaire completed at the bigening and at the end of the bed of treatment.
Main outcome variables
The average score of depression; The severity of depression

General information

Reason for update
change in part of the protocol
Acronym
IRCT registration information
IRCT registration number: **IRCT20211207053313N1**
Registration date: **2021-12-12, 1400/09/21**
Registration timing: **prospective**
Last update: **2023-10-10, 1402/07/18**
Update count: **1**
Registration date
2021-12-12, 1400/09/21

Registrant information
Name
Maryam Eradi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-10, 1400/10/20
Expected recruitment end date
2022-01-20, 1400/10/30
Actual recruitment start date
2022-03-06, 1400/12/15
Actual recruitment end date
2022-05-05, 1401/02/15
Trial completion date
2022-09-06, 1401/06/15

Scientific title
The effect of Matricaria Chamonail on postpartum depression

Public title
The effect of Matricaria Chamonail on postpartum depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a cell phone Women with mild to moderate

depression who are in the second week after delivery until 6 months later. Term, single and alive baby delivery Being literate Age 18 to 45 years Women with mild to moderate depression who are in the second week after delivery until 6 months later.

Exclusion criteria:

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **144**

Actual sample size reached: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be divided into two groups of 72 people in the chamomile extract group and the placebo group by random block allocation method and using 6 blocks. In order to prevent the occurrence of selection bias, the Allocation Concealment method will be used by placing the sample code in closed and two-layer envelopes and keeping these envelopes with the secretary of health centers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done in the form of double-sided blinds; In order to reduce the possibility of information bias, the capsules will be coded by the pharmaceutical company. Patients and individuals who provide drugs or evaluate the results of the treatment will be unaware of the type of treatment assigned to each person.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

No. 491, Imamat St., Jomhuri Eslami Blvd., Dezful Town

City

Dezful

Province

Khouzestan

Postal code

6461158753

Approval date

2021-11-23, 1400/09/02

Ethics committee reference number

IR.AJUMS.REC.1400.523

Health conditions studied

1

Description of health condition studied

Postpartum depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The average score of depression

Timepoint

Before the intervention nd 8 weeks after the start of treatment

Method of measurement

Beck Depression questionnaire

2

Description

The severity of depression

Timepoint

Before the intervention and 8 weeks after the start of treatment

Method of measurement

Beck depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People will be advised to take two capsules of 500 mg of chamomile extract daily. Patients will be contacted twice a week. at the first visit, capsules will be given to them to continue treatment until week 8. At the end, Beck questionnaire will be completed by them. 500mg chamomile capsules standardized with 1.2% flavonoid of Gol Darou company are prepared. Participants received 1,000 mg daily (twice daily) for 8 weeks

Category
Treatment - Drugs

2

Description
Control group: Placebo capsules filled with saccharin powder are provided by Gol Daroo Company. The capsules are similar in shape, size and packaging to the capsules containing chamomile extract. The capsules will be named by the pharmaceutical company. Participants will receive placebo twice a day for 8 weeks. Patients will be contacted twice a week. t. at the first visit, capsules will be given to them to continue treatment until week 8. At the end, Beck questionnaire will be completed by them.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health center No.4
Full name of responsible person
Maryam Eradi
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No. 491, Imamat St., Jomhuri Eslami Blvd.
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2

Recruitment center
Name of recruitment center
Health center No.1
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Farhangian health center
Full name of responsible person
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4

Recruitment center
Name of recruitment center
Modares No.2 health center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadimoghadam
Street address
Vice Chancery for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services, University Campus, Ahvaz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
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Position
Master student
Latest degree
Bachelor
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable