Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the effect of folic acid supplementation on postpartum depression in women referring to comprehensive health service centers in Mashhad and Gonabad in 2014-2014

Protocol summary

Study aim
Determining the effect of folic acid supplementation on postpartum depression in women referring to comprehensive health service centers in Mashhad and Gonabad in 1403-1402

Design
A clinical trial with a control group, a blind strain, randomized on 60 postpartum women

Settings and conduct
Astrology is available in Mashhad and Gonabad University of Medical Sciences and is performed in a randomized manner and is blinded and the study population is blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women on the 3rd-5th day after delivery, live baby, disease-free pregnancy, 10-54 years old, depression score less than 12, normal body mass index, regular use of pregnancy supplements, singleton pregnancy. Exclusion criteria: smoking or tobacco use, taking drugs other than supplements.

Intervention groups
Mothers in the intervention group were given 500 mg of folic acid tablets daily for 8 weeks. Mothers in the control group were given a placebo daily for 8 weeks.

Main outcome variables
Postpartum depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240107060642N1**
Registration date: **2024-01-30, 1402/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-30, 1402/11/10**
Update count: **0**

Registration date
2024-01-30, 1402/11/10

Registrant information

Name
Mahnaz Mohammadizadeh sarab

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4612 3001

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mh.mohamdizadeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-03-18, 1402/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of folic acid supplementation on postpartum depression in women referring to comprehensive health service centers in Mashhad and Gonabad in 2014-2014

Public title
Investigating the effect of folic acid supplementation on postpartum depression in women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy without disease (nervous problems, bipolar, depression, anxiety, epilepsy, lack of anencephaly or neural tube defects underlying diseases including: diabetes, blood pressure - hypothyroidism - hyperthyroidism) according to the mother's statement or health record Women on day 3-5 after giving birth Having a live baby Age 54-10 years People who have a normal body mass index in the first 12 weeks of pregnancy (18/24/5) and overweight during pregnancy in the normal range (11/5/16) Depression score less than 12 A singleton pregnancy Informed consent has been obtained Regular consumption of pregnancy supplements according to the instructions of the Ministry of Interior (from the 16th week to the end of pregnancy)

Exclusion criteria:

Use of drugs other than post-natal supplements according to the statement of the patient or the doctor of the center Smoking or smoking

Age

From **10 years** old to **54 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by the available method and using random allocation in two groups. Sampling method: multi-stage. First, the list of all the centers is prepared according to the 13 regions of Mashhad city, and then one or more centers will be randomly selected from each region according to the number of centers covered in that region. And the list of health service centers in Gonabad will be prepared and in the following, sampling will be done in selected centers according to the population of women giving birth under the cover of that center. In order to randomly assign the samples to each of the 2 intervention and control groups, 2.4 variable blocks are used. In this way, first 7 possible states of blocks (BBAA, BABA, ABBA, BAAB, AB, AABB, ABAB) are listed and numbers 1 to 7 are assigned to each block. Then, a number between 1 and 7 is randomly selected and then people are assigned to the group receiving additional folic acid supplement (B) and the control group (A) based on the block corresponding to the selected number. This work continues until the sample volume is completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Monetization will be (available) in a non-random way. In order to randomly assign the samples to each of the 2 intervention and control groups, 2-4 variable blocks are used. In this way, first, 7 possible states of blocks (BBAA, BABA, ABBA, BAAB, AB, AABB, ABAB) are listed and numbers 1 to 7 are assigned to each block. Then, a number between 1 and 7 is randomly selected, and then people are assigned to the folic acid supplement group (B) and the control group (A) based on the block corresponding to the selected number. This work continues until the sample volume is completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Khorasan Razavi-Chanaran-Imam Khomeini 27, No. 8

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Mashhad

Province

Razavi Khorasan

Postal code

93617-65834

Approval date

2023-12-25, 1402/10/04

Ethics committee reference number

IR.GMU.REC.1402.133

Health conditions studied

1

Description of health condition studied

Postpartum depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes

1

Description

depression score

Timepoint

Before the intervention, 1 and 2 months after start of the intervention

Method of measurement

Edinburgh depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 500 mg of folic acid tablets daily (take half of a tablet of 1 mg of folic acid), will be given for 8 weeks.
Category
Prevention

2

Description
Control group: And mothers of the control group will be advised to use a placebo daily for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad and Gonabad comprehensive health service center
Full name of responsible person
Mahnaz Mohammadizadeh
Street address
No. 8, 27 Imam Khomeini Planar, Khorasan Razavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
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Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Personal
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Mahnaz Mohammadizadeh
Position
Midwifery Master's student
Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Title and more details about the data/document
I would like to share some data
When the data will become available and for how long
I do not set a time frame
To whom data/document is available
I did not make a decision at this time
Under which criteria data/document could be used
I did not make a decision at this time
From where data/document is obtainable
Refer to the email address
What processes are involved for a request to access data/document
Refer to the email address
Comments