

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 Mohammadzadeh sarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4612 3001

Email address

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

City

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

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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

Mahnaz Mohammadizadeh

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

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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