Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A Comparative Study of the Effects of Folic Acid and Vitamin B6 in the Prevention of Postpartum Depression in Mothers at Risk of Postpartum Depression

Protocol summary

Study aim
Determining the effect of folic acid and vitamin B6 in the prevention of postpartum depression in mothers at risk of postpartum depression

Design
A double-blind clinical trial study with placebo and randomized block in three groups on 105 patients

Settings and conduct
The present study is a double-blind placebo-controlled clinical trial study. Blinding of this study is established between the patient and the researcher. Also, the person evaluating the course of the depression will not know the belonging of the people to the three groups. Participants (pregnant women) aged 18 to 45 and in the third trimester of pregnancy will be selected in the health centers of Isfahan city. Selected people in three separate groups (two intervention groups and one control group) are subjected to intervention with vitamin B6, folic acid and placebo. Medicines and placebo are packed inside capsules of the same shape and color so that they cannot be distinguished for clients. Depression and social support are measured in this research by means of a questionnaire and an interview method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Pregnant women aged 18 to 45 years. 2- Women should be in the third trimester of pregnancy. Exclusion criteria from the research: 1- Women who give birth under 37 weeks. 2- have a score below 7 and a score above 15 for anxiety or depression based on the HADS screening questionnaire. 3- Lack of consent to participate in the study.

Intervention groups
Selected people in three separate groups (two intervention groups and one control group) are subjected to intervention with vitamin B6, folic acid and placebo.

Main outcome variables
Postpartum depression score based on the Edinburgh Postpartum Depression Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090801002266N19**
Registration date: **2023-03-28, 1402/01/08**
Registration timing: **prospective**

Last update: **2023-03-28, 1402/01/08**
Update count: **0**

Registration date
2023-03-28, 1402/01/08

Registrant information

Name
Gholamreza Kheirabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 1222 2135

Email address
kheirabadi@bsrc.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-05-20, 1403/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparative Study of the Effects of Folic Acid and Vitamin B6 in the Prevention of Postpartum Depression in Mothers at Risk of Postpartum Depression

Public title
"Effect of folic acid and vitamin B6"; "Prevention of postpartum depression"

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women 18 to 45 years old Women should be in the third trimester of pregnancy. People have a previous history of depression or anxiety based on history. People have a positive family history of depression. 7 to 15 anxiety or depression score based on HADS screening questionnaire People have a low or very low social support score in the NSSQ social support questionnaire.
Exclusion criteria:
Women who give birth under 37 weeks. Women who have a score below 7 and a score above 15 of anxiety or depression based on the HADS screening questionnaire. Lack of consent to participate in the study Women with treatment for depression or any type of psychiatric disorder Women under medical treatment due to high-risk pregnancy Women with limited mobility due to high-risk pregnancy Women with a history of receiving folic acid at a dose greater than 1 mg per day or a history of receiving B6 daily

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

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
People are selected by simple randomization and in the order of visiting health centers where the plan is implemented and if they agree. These people are placed in groups of three in blocks of three, and the people of each block are placed in one of the three intervention groups by simple random selection of envelopes containing numbers 1 to 3.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is a double-blind clinical trial study with placebo. Medicines and placebo are packed inside capsules of the same shape and color so that they cannot be distinguished for clients.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-11-27, 1401/09/06

Ethics committee reference number
IR.MUI.MED.REC.1401.314

Health conditions studied

1

Description of health condition studied
Postpartum Depression

ICD-10 code
F53

ICD-10 code description
Puerperal psychosis

Primary outcomes

1

Description
Postpartum depression score based on the Edinburgh Postpartum Depression Scale

Timepoint
before the intervention and one and a half months after delivery

Method of measurement
In this research, it is measured by questionnaire and interview method. These questionnaires include 1- Demographic Characteristics Questionnaire 2- HADS 2 Questionnaire 3- Edinburgh Depression Questionnaire 4- Social Support Questionnaire (NSSQ).

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: 35 people receiving 2 tablets of B6 (Prepared from Amin Pharmaceutical Factory), 40 mg daily, from the 26th week of pregnancy until the end of pregnancy; After giving birth, 1 tablet of B6, 40 mg daily, for one month.
Category
Treatment - Drugs

2

Description
Intervention group: 35 people receiving 2 tablets of folic acid 1 mg daily (Prepared from Amin Pharmaceutical Factory), food from the 26th week of pregnancy until the end of pregnancy; After giving birth, 1 tablet of folic acid 1 mg per day for one month.
Category
Treatment - Drugs

3

Description
Control group: 35 people receiving 2 placebo tablets (Prepared from Amin Pharmaceutical Factory) daily from the 26th week of pregnancy until the end of pregnancy; After delivery, 1 placebo tablet daily for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan city health centers
Full name of responsible person
Gholam Reza Kheirabadi
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Fax
+98 31 3668 0048
Email
kheirabadi@bsrc.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Fax
+98 31 3668 0048
Email
kheirabadi@bsrc.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Position
Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province

Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
kheirabadi@bsrc.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Position
Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
kheirabadi@bsrc.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Position
Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
kheirabadi@bsrc.mui.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
The access period starts one year after publication of the results
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
After the publication of the results in the form of an article and with full observance of the confidentiality of the data in such a way that the data related to each person cannot be identified individualy.
From where data/document is obtainable
kheirabadi@bsrc.mui.ac.ir Gholam Reza Kheirabadi Professor of Psychiatry Department of Psychiatry, School of Medicine Behavioral Sciences Research Center Nour & Ali-Asghar Hospital Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
Send an email to the project manager
Comments