

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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**

Isfahan

**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

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

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+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

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##### Postal code

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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

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

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## 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**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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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

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 individually.

### 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