

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of prescribed vitamin B6 for depression among “mothers at risk for postpartum depression” during the third trimester at selected health care centers Isfahan city 2016.

Protocol summary

Summary

The aim of this study was to investigate the effect of prescribed vitamin B6 for depression among “mothers at risk for postpartum depression” during the third trimester at selected health care centers Isfahan city 2016. This single blind clinical trial study was conducted via using placebo. The participants were selected at six health centers in Isfahan City. Pregnant women 18-45 years old, primi or multi porous, singleton at week 28 of pregnancy, without current prenatal depression. Including loss of sample size for each group was of 40 Pregnant women. Inclusion criteria: The criterion for entering this study was at least one risk factor of postpartum depression; physical health of pregnant mother; lack of current depression. Exclusion criteria: prenatal depression at third trimester; unwillingness to continue the study at any time .Simple random sampling, qualified inclusion in the study are placed in two groups, Case group and Control group. Case group {40 subjects receiving 2 tablets B6 (40mg,oral) daily from week 28 till end pregnancy; after delivery 1 tablet B6 (40mg,oral) daily for one month and Control group {40subjects receiving placebo 2 tablets(oral) daily from week 28 till end pregnancy, after delivery receiving placebo 1 tablet(oral) daily for a month{received. Depression was evaluated via Edinburgh Standard questionnaire. Results in 2 stages, before intervention and 1.5 month after delivery will be evaluated. Questionnaires were completed by research's units. The main outcome evaluated in this study changes Postpartum depression score in research's units.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091929873N1**

Registration date: **2016-11-05, 1395/08/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-05, 1395/08/15

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-02-24, 1394/12/05

Expected recruitment end date

2016-04-08, 1395/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prescribed vitamin B6 for depression among “mothers at risk for postpartum depression” during the

third trimester at selected health care centers Isfahan city 2016.

Public title

The effect of vitamin B6 in the prevention of postpartum depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The criterion for entering this study was at least one risk factor of postpartum depression; physical health of pregnant mother; lack of current depression. Exclusion criteria: prenatal depression at third trimester; unwillingness to continue the study at any time

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Street , Isfahan

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Postal code

8199939438

Approval date

2016-02-24, 1394/12/05

Ethics committee reference number

IR.MUI.REC.1394.3.970

Health conditions studied

1

Description of health condition studied

postpartum depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

postpartum depression

Timepoint

The depression was evaluated baseline before intervention /and 1.5 month after delivery.

Method of measurement

Edinburgh standard questioner

Secondary outcomes

empty

Intervention groups

1

Description

Case group receive {2 tablets B6 (40mg; oral) daily; from week 28 till end pregnancy; after delivery1 tablet B6 (40mg; oral) daily for one month}. Every two weeks, Researcher phone calls to ensure, they were reminded of pills on phone and mentioned the subjects' use of pill. Edinburgh postpartum depression questionnaires were completed by research's units before intervention and 1.5 months after delivery.

Category

Placebo

2

Description

Control group receive { placebo 2 tablets oral ; daily from week 28 till end pregnancy, after delivery receiving placebo 1 tablet oral ; daily for a month} . The Placebo tablet has 6.2 mm in diameter and 100 mg weight and made from corn starch. The placebo tablet is Simulated of vitamin tablet B6 Amin pharmaceutical factory. Every two weeks, Researcher phone calls to ensure, they were reminded of pills on phone and mentioned the subjects' use of pill. Edinburgh postpartum depression questionnaires were completed by research's units before intervention and 1.5 months after delivery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

TheValieacr Haelth Center

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Research Department of Medical Sciences

Full name of responsible person

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Isfahan University of Medical Sciences, Building
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Grant name

جاری تحقیقات دانشگاه

Grant code / Reference number

1805003000

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan Research Department of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Science

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*