Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effect of oral vitamin B6 on common complaints of first trimester pregnancy in women referred to community health centers in Gonabad in 2019-2020

Protocol summary

Study aim

The effect of oral vitamin B6 on common complaints in the first trimester of pregnancy to the community health centers in 2019-2020

Design

Randomized control trial, double-blind, parallel group

Settings and conduct

After obtaining permission, a list of pregnant mothers will be requested by Gonabad comprehensive health centers for 6-10 weeks pregnant. The women will be contacted and invited to meet in person. If you wish to participate in the study, written informed consent will be obtained after an oral explanation of the research. Pre-intervention questionnaires including standard questionnaires for pregnancy nausea and vomiting, edinburgh depression, multidimensional fatigue, sleep quality, and visual analog scale will be administered to mothers. It should be noted that the questionnaires will be filled before and after the intervention in the presence of the researcher. Samples will be randomly assigned to blocks A and B in a randomized block design and divided into two groups of 40 mg vitamin B6 and a placebo. Tablets will be used in the same packaging as Code A and B. After 4 days, 24-hour pregnancy nausea and vomiting questionnaire will be given to research units and after one month, Other questionnaires will be given.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All low-risk pregnant women 10-6 weeks with fatigue, poor sleep quality, mild to moderate nausea and vomiting, depression score less than 12, breast pain and lack of anemia Exclusion criteria: unwillingness to continue studying and not taking pills and abortion

Intervention groups

The control group: placebo received one dose daily for 30 days, and the intervention group received vitamin B6 40 mg daily for 30 days.

Main outcome variables

The effect of vitamin B6 on nausea and vomiting, fatigue, breast pain, sleep quality and depression score in the first trimester of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190730044382N2**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Asma Salar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5728 8961

Email address

salar.a.stu@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral vitamin B6 on common complaints of first trimester pregnancy in women referred to community health centers in Gonabad in 2019-2020

Public title

Effect of oral vitamin B6 on common complaints of first trimester pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-40 years Pregnancy age 6-10 weeks Low risk pregnancy Depression score less than 12 Lack of physical and mental illness Use supplements the first trimester of pregnancy (iodopholic and vitamin D3) No breastfeeding Knowing how to read and write Hemoglobin greater than 11 gr/d Breast pain with pregnancy starting for 5 days or more Pregnancy wanted No history of stillbirth No history recurrent abortion No history of infertility Do not used B6 supplementation before recent pregnancy Normal body mass index (18.5-24.9) No employment in night shift Sleep quality score of 5 or more Fatigue score greater than one Mild to moderate nausea and vomiting score (score 3-12)

Exclusion criteria:

Not using vitamin B6 in intervention group Not using placebo in control group Abortion or medical termination of pregnancy Unwillingness to participate in follow-up study. Not filling questionnaires during the study Pregnancy twins or moles Receiving new medication during the study.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

For sampling, each person will be selected for inclusion in the study, and then the samples will be divided into two intervention groups (A (or control) B) based on 4-block design and random allocation. A 4-block block will be used for sampling (AABB, ABAB, BBAA, BABA).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study vitamin B6 and placebo will be prepared in packages including 30 tablets as A and B. Due to the method of the study, the research unit and the researcher have no information about each package; it means that placebo (manufactured by Mashhad School of Pharmacy) and vitamin B6 tablets is provided in A and B packages that are completely similar. These packages are prepared by another person (not the researcher) then are given to the researcher. After explaining phases of the research to the research units and obtaining written consent will be placed in two groups of intervention and control based on random block allocation. 4-block packages will be used for sampling (AABB, ABAB, BBAA, BABA).

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

Asian Road Margin, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

۹۶۹۱۷۹۳۷۱۸

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.GMU.REC.1398.159

Health conditions studied

1

Description of health condition studied

Common complaints in the first trimester of pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of vitamin B6 on breast pain

Timepoint
Measurement of breast pain at the beginning and end of the study
Method of measurement
The Visual Analogue Scale Questionnaire is a standard instrument measuring a 10 cm ruler. Depending on the amount of pain, the person signs on the continuum for the past 48 hours. The Linear-Visual Measurement Scale of Pain is classified as 0 to 10 as follows: 0: No pain, 3-1: Mild pain, 4-6: Moderate pain, 10-7: Severe pain

2

Description
The effect of vitamin B6 on depression score in pregnant women
Timepoint
At the beginning and end of the study
Method of measurement
The Edinburgh Depression Questionnaire is used to measure depression during pregnancy and postpartum. The tool has 10 four-choice questions and each question has a score of 0-3 and its overall score ranges from 0-30. In Iran, a score of 12 or higher is a sign of mothers' depression

3

Description
The effect of vitamin B6 on sleep quality of pregnant women
Timepoint
At the beginning and end of the study
Method of measurement
Petersburg Sleep Quality Questionnaire (PSQI) One of the best tools designed to measure sleep quality is the Petersburg Sleep Quality Questionnaire (PSQI). The sum of the 7 subscale scores will be between 0 and 21. Getting a total score above 5 on the whole questionnaire means poor sleep quality.

4

Description
The effect of vitamin B6 on fatigue in pregnant women
Timepoint
At the beginning and end of the study
Method of measurement
Multidimensional Fatigue Scale (MAF) Questionnaire, which is used to measure fatigue and is capable of measuring fatigue in pregnant women.

5

Description
The effect of vitamin B6 on pregnancy nausea and vomiting
Timepoint
At the beginning and 4 days after the start of the study
Method of measurement
The 24-hour Pregnancy Nausea and Vomiting Questionnaire (PUQE-FORM-24) consisted of three questions that measured the duration of nausea, vomiting time, and frequency of frustration over the past 24 hours, with scores ranging between 15 and 3. Less than or equal to 6 indicates mild nausea and vomiting, moderate nausea and vomiting 7-12 and more or less than 13 severe forms.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral vitamin B6 tablet 40 mg, daily for 30 days Manufactured by Iran Hormone Company
Category
Treatment - Drugs

2

Description
Control group: One 40 mg tablet containingstarch daily for 30 days, manufactured by Mashhad School of Pharmacy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Community Health Center Number One
Full name of responsible person
Asma Salar
Street address
Next to Blood Transfusion Organization, Emam Khomeiny Ave, Ghadir Square
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2

Recruitment center
Name of recruitment center
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3

Recruitment center
Name of recruitment center
Health Center No. 3- A
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
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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
Undecided - It is not yet known if there will be 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
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