

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of vitamin B6 consumption in comparison with placebo on sleep disorder in the third trimester of pregnancy in pregnant women

#### Protocol summary

##### Study aim

Comparison of prevalence of sleep disorders in third trimester pregnant in groups 1 and 2 after intervention

##### Design

A randomized controlled clinical trial with double blinded parallel groups (Blocking) design of 100 people

##### Settings and conduct

This study is a double-blind clinical trial. The study population consisted of all pregnant women who were referred to Sabzevar health centers during the weeks 32-32 of pregnancy. After obtaining permission from the Ethics Committee of Sabzevar University of Medical Sciences and obtaining written consent, 100 mothers were asked to complete the Sleep Quality Index Questionnaire in Sabzevar Vase Hospital.

##### Participants/Inclusion and exclusion criteria

Enter: Women between the ages of 28 and 32 weeks gaining a score of 5 and higher in the Pittsburgh questionnaire and women's willingness to participate in the study. Exit: Existence of underlying disease, having a special diet and taking supplements other than supplements pregnancy, narcotic products using

##### Intervention groups

Intervention group Vitamin B6 80 mg single dose per night (based on midwifery reference books, the maximum allowed dose is 1.9 mg / kg body weight, and therapeutic efficacy of up to 3 doses of 40 mg has been used in the literature). The control group received a placebo made by a factory of shape, color, taste and convexity similar to the intervention group, and the mothers were instructed to consume 2 pills each night.

##### Main outcome variables

Third trimester sleep disorders

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190718044257N1**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

##### Registration date

2020-08-21, 1399/05/31

##### Registrant information

##### Name

Zahra Iziy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4413 4154

##### Email address

zboroghani1996@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-01, 1398/10/11

##### Expected recruitment end date

2020-07-01, 1399/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of vitamin B6 consumption in

comparison with placebo on sleep disorder in the third trimester of pregnancy in pregnant women

**Public title**

effect of vitamin B6 on sleep in pregnancy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with gestational age of 28-32weeks Get a score of 5 or higher on the Pittsburgh questionnaire Women's willingness to participate in the study No history of sleep disorders before pregnancy Ladies working without night shift Female 18 to 35 years No history of infertility

**Exclusion criteria:**

Existence of mom's underlying disease Taking sleeping pills History of pre\_pregnancy sleep disorders Know complication of pregnancy Narcotic products using Having a special diet Get a score of 40 or higher on the Spielberger questionnaire Working lady with night working hours

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: 96

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Stratified sampling: 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 will be used for sampling (AABB, ABAB, BBAA, BABA)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study was administered to the intervention group and the placebo control group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

**Street address**

Sabzevar.tohidshar. block6. Hekmat avenue,hekmat 12

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617975719

**Approval date**

2020-02-01, 1398/11/12

**Ethics committee reference number**

IR.MEDSAB.REC.1398.093

**Health conditions studied**

1

**Description of health condition studied**

sleep disorders

**ICD-10 code**

F51.0

**ICD-10 code description**

بی خوابی غیر ارگانیک بارداری

**Primary outcomes**

1

**Description**

Sleep Quality Score in Pittsburgh Sleep Quality Questionnaire

**Timepoint**

Before intervention-One week after intervention

**Method of measurement**

Pittsburgh Sleep Quality Index Questionnaire

**Secondary outcomes**

1

**Description**

improve sleep disorders of pregnant women

**Timepoint**

Third trimester of pregnancy

**Method of measurement**

Completing the questionnaire

**Intervention groups**

1

**Description**

Intervention group: A group that consumes 80 mg of vitamin B6 per night in a single dose for a week, so that mothers are taught to take 2 pills every night before bed, one week after the intervention, the mothers are contacted for a visit.

**Category**

Treatment - Drugs

## 2

### Description

Control group: The group that takes placebo(made by a factory with the same shape, size, color, taste, convexity and logo as the intervention group) for a week, and mothers are taught to take 2 pills every night before bed, and will be visited the next week.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Specialty Perinatology Clinic of Vasei Hospital,  
Sabzevar, Iran

##### Full name of responsible person

Zahra Iziy

##### Street address

No.12, Amirfazli 8, Amirfazli St..., Rezvan Town,  
Sabzevar

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

780920481

##### Phone

+98 51 4413 4154

##### Email

zaryy.iziy.79@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mitra Eftekhariyazdi

##### Street address

North Kashafi Street ,Sabzevar , Khorasan Razavi

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

961791314

##### Phone

+98 51 4423 8100

##### Email

m\_eftekhari1144@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mojdehnavinejad

##### Position

Master of Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

No. 13, Shirin alley, Ibn Yemen 45, Ibn Yemen Ave,  
Sabzevar

##### City

sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613883778

##### Phone

+98 51 4423 3808

##### Email

mojdemw@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mojdeh Navinejad

##### Position

master of midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

No. 13, Shirin alley ,Ibn Yemen 45 Ibn Yemen  
Ave,Sabzevar

##### City

Sabzevar

##### Province

Razavi Khorasan  
**Postal code**  
9613883778  
**Phone**  
0098 44233803  
**Email**  
mojdemw@gmail.com

Razavi Khorasan  
**Postal code**  
780920481  
**Phone**  
+98 51 4413 4154  
**Email**  
zaryy.iziy.79@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Zahra Izziy  
**Position**  
University student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
No. 12, Amirfazli 8 , Amirfazli St... , Rezvan Town ,  
Sabzevar  
**City**  
Sabzevar  
**Province**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not 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