# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 2after 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 Vasie 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 speacial diet and taking supplemants other than supplemants 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 dosed 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**
zborooghani1996@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 an 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 speacial 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**
mprove 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 befor 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 befor 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

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

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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

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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

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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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