

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The impact of Myo-inositol supplementation with sleep hygiene education on sleep quality in pregnant women

#### Protocol summary

##### Study aim

The impact of Myo-inositol supplementation with sleep hygiene education on sleep quality in pregnant women

##### Design

In this study, 60 pregnant women with a gestational age of at least 14 weeks who are referred to the Obstetric and Gynecology Clinics of Babol are selected. The participants were divided With a block size of 4, into two groups of A and B (intervention and control) by selecting the number of (0 - 6) are randomly assigned using computer software.

##### Settings and conduct

In this study, the participants, in case of severe depression and severe stress according to the Beck Depression Inventory and Perceived Stress Scale questionnaire are excluded. The subjects in both groups were asked to complete a demographic questionnaire, sleep quality, and sleep Hygiene index and then is given sleep hygiene education. Women were randomly divided into two groups, in group 1 (n=30), people treated with myoinositol supplementation powder and the control group (n=30) received placebo for a total of 10 weeks. Evaluation (replenishment of the sleep hygiene questionnaire, sleep quality questionnaire) and determining the side effects of the drug in the second trimester in weeks (24-28) and evaluation in the third trimester in the weeks (37-38).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age of 14 weeks; absence of chronic diseases; no history of sleep disorders before pregnancy; no history of abortion in previous pregnancies. Exclusion criteria: severe depression or severe stress; death experience of one of the first-degree relatives during pregnancy, and changes in sleep status due to travel.

##### Intervention groups

Interventions group: myoinositol supplementation powder (myoinositol + folic acid) Control group: placebo (folic acid + wheat flour)

##### Main outcome variables

Sleep quality; neonatal and pregnancy outcomes and side effect of drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160208026446N3**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-29, 1398/06/07**

Update count: **1**

##### Registration date

2018-06-03, 1397/03/13

##### Registrant information

##### Name

Mouloud Agajani Delavar

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3236 0714

##### Email address

m.aghajani@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-07, 1397/01/18

##### Expected recruitment end date

2019-02-19, 1397/11/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The impact of Myo-inositol supplementation with sleep hygiene education on sleep quality in pregnant women

**Public title**

The impact of Myo-inositol supplementation with sleep hygiene education on sleep quality in pregnant women

**Purpose**

Prevention

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

Conscious written consent Pregnant women with single pregnancy Age 18 and over Gestational age of 14 weeks Absence of chronic physical diseases such as diabetes, high blood pressure and cardiovascular disease No history of taking prenatal drugs before pregnancy No history of sleep disorders before pregnancy Working women without night shift work Non-smoking and alcohol Lack of history of psychiatric use No history of abortion in previous pregnancies

**Exclusion criteria:**

Severe depression or severe stress Death experience of one of the first-degree relatives during pregnancy Changes in sleep status due to travel

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Blocked randomization with a block size of 4, for two groups (A, B). Random numbers (0 - 6) was generated using computer software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Blind groups include: participant, clinical caregiver, researcher, outcome evaluator, data analyst. Double blind study. Medications and placebo are coded by someone other than the investigator as group (1 and 2) and the investigator do not know which group is related to the drug. The subjects are satisfied and informed that they may be Instead of medication, placebo is given to them. The distribution method With a block size of 4, for two groups (A, B). Random numbers (0 - 6) was

generated using computer software

**Placebo**

Used

**Assignment**

Parallel

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

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic Committee of Babol University of Medical Sciences

**Street address**

Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran

**City**

Mazandaran

**Province**

Mazandaran

**Postal code**

47176-47745

**Approval date**

2018-05-19, 1397/02/29

**Ethics committee reference number**

IR.MUBABOL.HRI.REC.1397.032

**Health conditions studied****1****Description of health condition studied**

Sleep quality in pregnancy

**ICD-10 code**

G47

**ICD-10 code description**

Sleep disorders

**Primary outcomes****1****Description**

Sleep Quality Score in Pittsburgh Sleep Quality Questionnaire

**Timepoint**

In the second trimester of pregnancy at weeks 24 to 28 and in the third trimester of pregnancy at weeks 37 to 38 of pregnancy.

**Method of measurement**

Pittsburgh Sleep Quality Index Questionnaire

**Secondary outcomes**

## 1

### Description

Neonatal and pregnancy outcomes

### Timepoint

The end of pregnancy for the outcome of pregnancy and infancy Method of measurement

### Method of measurement

Questionnaire and complete the checklist using file.

## 2

### Description

Side effect of drug

### Timepoint

In the second trimester of pregnancy (week 24-28) and the third trimester of pregnancy (week 37\_38)

### Method of measurement

Drug side effect checklist

## Intervention groups

### 1

#### Description

Intervention group: myoinositol supplementation powder the ino folic commercial name containing 2000 mg of myoinositol and 200 µg of folic acid (manufactured by the company Lo.Li Pharma ) once a day (one sachet per night in a glass of water is dissolved) from gestational age 14 to 24 weeks)

#### Category

Prevention

### 2

#### Description

Control group: placebo (folic acid powder 400 mcg + wheat flour total 2 grams) Once a day (one hour a sachet is dissolved in a glass of water) from the gestational age 14 weeks to 24 weeks for a total of 10 weeks .

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Obstetrics and Gynecology Clinics of Babol

##### Full name of responsible person

Molood Aghajani Delavar

##### Street address

Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran

##### City

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##### Province

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##### Postal code

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##### Email

moloodaghajani@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Ali Bijani

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##### Phone

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##### Email

alibijani@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Babol 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

Babol University of Medical Sciences

##### Full name of responsible person

Molood Aghajani Delavar

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**  
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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

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable