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)

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