Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The Impact of Myo- inositol supplementation to prevent gestational diabetes in overweight pregnant women

Protocol summary

Study aim

Determine the effect of myo_inositol supplementation to prevent gestational diabetes in overweight pregnant women.

Design

114 pregnant women who are referred to the obstetric clinics are selected. The participants were divided With a block size of 4, into two groups of A and B by selecting the number of (0 - 6) are randomly assigned.

Settings and conduct

The participants, if the fasting glucose is less than 92 mg / dl or randomized glucose is less than 200, and other conditions for entry into the study are included.Triglyceride, cholesterol, LDL, HDL, fasting blood sugar , fasting insulin, insulin sensitivity are checked according to routine laboratory tests and then them randomly divided into two groups. In group A (n = 30), people treated with myo-inositol of folic acid once a day from the gestational age of and the group B (n = 30) are received placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Written consent, pregnant women with singleton pregnancy, age above 18 years old, gestational age 14 weeks, per-pregnancy BMI >= 25 and less than 30 kg /m2, fasting glucose less than 92 mg /dL or Random glucose less than 200 mg /dL, no chronic diseases, non-smoking and alcohol. Exclusion criteria: The death experience of one of the first-degree relatives during pregnancy, treatment with corticosteroid during pregnancy.

Intervention groups

Intervention group: Myo-inositol containing 2000 mg of myo-inositol and 200 µg of folic acid (manufactured by the company Lo.Li Pharma) once a day from the gestational age of 14 weeks to 24 weeks Control group: Placebo (folic acid powder 400 mcg + wheat flour total 2 grams) once a day from the gestational age 14 weeks to 24 weeks

Main outcome variables

primary outcome: Gestational diabetes mellitus (Abnormal oral glucose tolerance test). Secondary outcomes: Neonatal and pregnancy outcomes and side effect of drug

General information

Reason for update

Revising sentence errors

Acronym

IRCT registration information

IRCT registration number: **IRCT20160208026446N2**
Registration date: **2017-12-14, 1396/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-15, 1398/07/23**
Update count: **1**

Registration date

2017-12-14, 1396/09/23

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

Babol University of Medical Sciences,Governmental

Expected recruitment start date

2017-12-05, 1396/09/14

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Myo- inositol supplementation to prevent gestational diabetes in overweight pregnant women

Public title

The Impact of Myo- inositol supplementation to gestational diabetes in overweight pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious written consent Pregnant women with singleton pregnancy Age above 18 years old Gestational age 14 weeks Pr-pregnancy BMI>= 25 and less than 30 kg / m 2 Fasting glucose less than 92 mg / dL or Random glucose less than 200 mg / dL No chronic diseases such as diabetes, high blood pressure and cardiovascular disease Non-smoking and alcohol

Exclusion criteria:

The death experience of one of the first-degree relatives during pregnancy Treatment with corticosteroids during pregnancy

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

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2017-08-20, 1396/05/29

Ethics committee reference number

MUBABOL.HRI.REC.1396.82

Health conditions studied

1

Description of health condition studied

Diabetes mellitus arising in pregnancy

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description

Triglyceride

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

2

Description

Total cholesterol

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

3

Description

LDL

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

4

Description

HDL

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

5

Description

Fasting blood sugar

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

6

Description

Glucose tolerance test of 1 and 2 hours with 75 g of oral glucose

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

7

Description

Fasting insulin

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

8

Description

Insulin sensitivity

Timepoint

In the second trimester of the week(24-28)

Method of measurement

Testes based on laboratorial rutine(Detailed description in the proposal)

Secondary outcomes

1

Description

Neonatal and pregnancy outcomes

Timepoint

The end of pregnancy for the outcome of pregnancy and infancy

Method of measurement

Questionnaire and complete the checklist using patient 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 fulic 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)

Category

Prevention

2

Description

: 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 . Control group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Prenatal Centers of Hospitals Affiliated to Babol University of Medical Sciences

Full name of responsible person

Molood Aghajani Delavar

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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
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Mazandaran
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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
Mouloud Agajani Delavar
Position
PhD in Womens Health
Latest degree
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Other areas of specialty/work
Gynecology and Obstetrics
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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
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