Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 2026

The effect of myoinositol supplementation on the prevention of gestational diabetes mellitus in high-risk women

Protocol summary

Study aim
The aim of this study was to evaluate the effect of myoinositol on gestational diabetes in high risk women.

Design
This is a randomized, multi-center, clinical trial with parallel groups. Our sample size is 276 people.

Settings and conduct
This randomized trial will be conducted on 276 eligible women, attending to Shariati and Arash hospitals. Fasting blood glucose and oral glucose tolerance test (GTT 75gm) and HbA1c tests will be performed for all women and they will be randomly divided into two groups. All participants will be tested again for GTT 75gm in 24- 28 gestational weeks. Then they will be followed up to the end of the pregnancy.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: family history of type 2 diabetes, previous history of GDM, glucosoria, glucose metabolism disorder and a history of infant macrosomia.

Intervention groups
Group 1 will receive 2 gr of myoinositol plus 200 micro gr of folic acid, twice a day orally from the 14th week of gestation until the 28th week. The second group will receive 200 micro gr folic acid twice a day orally.

Main outcome variables
the rate of gestational diabetes and other side effects of gestational diabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120826010664N4**
Registration date: **2019-05-08, 1398/02/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-17, 1403/05/27**
Update count: **1**

Registration date
2019-05-08, 1398/02/18

Registrant information
Name
Reihaneh Pirjani
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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+98 21 7788 3288
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pirjani@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Science

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of myoinositol supplementation on the prevention of gestational diabetes mellitus in high-risk women

Public title
The effect of myoinositol supplementation on the prevention of gestational diabetes mellitus

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

BMI>30 Family history of type 2 diabetes Previous history of GDM Glucosoria Glucose metabolism disorder history of infant macrosomia

Exclusion criteria:

History of diabetes mellitus Multiple pregnancy Acute infection during pregnancy Impaired GTT in first-trimester routine tests

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **276**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 276, with 138 participants in each group. Given the multi-central design of the study, 138 patients in each center will be selected according to the following manner. We have two randomization lists with a length of 138 (69 participants in each group) that the number of treatments in each list is equal, with a 1:1 ratio. Block randomization method will be designed by the head epidemiologist using STATA software version 13. The number of blocks considered is 6.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences , Deputy of Research

Street address

Qods Street, Keshavarz Bulevard

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-10-01, 1398/07/09

Ethics committee reference number

IR.TUMS.VCR.REC.1398.618

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus (GDM)

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

Primary outcomes

1

Description

gestational diabetes mellitus

Timepoint

24- 28 weeks of pregnancy

Method of measurement

glucose tolerance test

Secondary outcomes

1

Description

type of delivery

Timepoint

end of pregnancy

Method of measurement

observational

2

Description

Macrosomia

Timepoint

After child birth

Method of measurement

observational

3

Description

preterm labor

Timepoint

end of pregnancy

Method of measurement

observational

4

Description

Preeclampsia

Timepoint

end of pregnancy

Method of measurement

observational

5

Description
premature rupture of membranes (PROM)
Timepoint
end of pregnancy
Method of measurement
observational

6

Description
Intrauterine growth restriction (IUGR)
Timepoint
end of pregnancy
Method of measurement
observational

Intervention groups

1

Description
Intervention group: 2 gr of myoinositol plus 200 micro gr folic acid twice a day orally, from 14th week of gestation until 28th week.
Category
Treatment - Drugs

2

Description
Control group: 200 micro gr folic acid twice a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women Hospital
Full name of responsible person
Dr Reyhaneh Pirjani
Street address
Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran.
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2

Recruitment center
Name of recruitment center
Yas Hospital Complex
Full name of responsible person
Dr Laleh Eslamian
Street address
Tehran Province, Tehran, District 7, N Villa Rd
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1598718311
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad Ali Sahraian
Street address
Tehran University of Medical Science, Qods street, Keshavarz boulevard
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rmo@tums.ac.ir
Web page address
http://vcr.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
1
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

2

Sponsor

Name of organization / entity

Health Parsian

Full name of responsible person

Dr Melina Makhmour Najafabadi

Street address

No. 492, Unit 16, Dowlat St, Pasdaran St, Teharn, Iran

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info@healthparsian.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Health Parsian

Proportion provided by this source

99

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Reihaneh Pirjani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

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Web page address

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 decision yet.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available