

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 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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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 Boulevard

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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