Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Assessment of the probiotic effectiveness on the rate of gestational diabetes in comparison to placebo in high risk pregnant women referred to Arash Hospital

Protocol summary

Summary

This study is a double blind randomized, parallel single-center clinical trial which is done in stage two of clinical trial.The aim of this study was to evaluate the effect of probiotic intake on diabetes in pregnancy. Singleton pregnant women aged between 18 -35 year- old enter the study based on inclusion criteria. Our sample size is 572 which are randomly divided into two groups. In intervention group, pregnant women receive probiotic tablets once a day for 10 weeks from 14th week of pregnancy. In control group, placebo is received the same as intervention group. Then, gestational diabetes in both groups is diagnosed by glucose tolerance test. Results of two groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110111020N6**
Registration date: **2016-12-26, 1395/10/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-26, 1395/10/06

Registrant information

Name
Maryam Khoshideh
Name of organization / entity
Tehran University of Medical Sciences, Arash Hospital
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khooshide@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the probiotic effectiveness on the rate of gestational diabetes in comparison to placebo in high risk pregnant women referred to Arash Hospital

Public title

Effect of probiotic in gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnant women in the first trimester; BMI more than 25; family history in the first-degree relatives; history of GDM in previous pregnancy; ovarian poly cystic syndrome; history of IUFD birth; Macrosomia; abortion Exclusion criteria: diabetes; heart and CNS diseases; using nerve drugs; multiple pregnancy; positive result of 75 grams glucose test in the first visit

Age

From **18 years** old to **35 years** old

Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **542**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Tehran University of Medical Science, Qods Street, Keshavarz Boulevard
City
Tehran
Postal code
Approval date
2016-10-25, 1395/08/04
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.857

Health conditions studied

1

Description of health condition studied
gestatinal diabetes mellitus
ICD-10 code
O24.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
gestational diabetes
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
weighting

3

Description
preeclampsia
Timepoint
during pregnancy
Method of measurement
measuring blood pressure and proteinuria

Intervention groups

1

Description
Intervention group: Patients receive probiotic tablets from 14th week of pregnancy for 10 weeks.Then gestational diabetes is diagnosed by GGT in 24 - 28 weeks.
Category
Treatment - Drugs

2

Description
control group: Patients receive placebotablets from 14th week of pregnancy for 10 weeks.Then gestational diabetes is diagnosed by GGT in 24 - 28 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women Hospital
Full name of responsible person

Neda Aslani

Street address

Arash hospital, Rashid street, Tehranpars, Resalat highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Science

Full name of responsible person

Dr Masoud Younesian

Street address

Tehran University of Medical Science, Qods street, Keshavarz boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

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Position

gynecologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr. Maryam Khooshide

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obstetrician and gynecologist

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty