

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of probiotic yogurt and conventional yogurt in blood glucose control and outcomes of pregnancy in women with gestational diabetes

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of probiotic yogurt and conventional yogurt in control blood glucose and outcomes of pregnancy in women with gestational diabetes who were referred to Alzahra and Taleghani hospitals in tabriz

Design

A randomized clinical trial was conducted in two groups of control and intervention, blinded, 84 patients using randomized tables in two intervention groups (probiotic yoghurt recipients) and control group (receiving yogurt recipient).

Settings and conduct

The double-blind, randomized clinical trial was carried out on diabetic patients who referred to the diabetes clinic of Alzahra and Taleghani hospital Tabriz, Iran. The type of received intervention will be written given on paper and will be numbered in matt envelopes.

Participants/Inclusion and exclusion criteria

Pregnant women 24-24 weeks of gestational diabetes mellitus will be included in the study and will not be included, if they have a history of diabetes in previous pregnancy or abnormal fetal

Intervention groups

The subjects in the intervention group consume 300 g/d probiotic yogurt containing 106 colony of both Lactobacillus acidophilus and Bifidobacterium lactis bacteria. (Production of the Iranian milk company Pegah) for 8 weeks. Subjects in the control group consume 300g/d conventional yogurt.

Main outcome variables

Hemoglobin A1c: Fasting Blood Sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121224011862N2**

Registration date: **2018-05-19, 1397/02/29**

Last update: **2018-05-19, 1397/02/29**

Update count: **0**

Registration date

2018-05-19, 1397/02/29

Registrant information

Name

Farnaz Sahaf

Name of organization / entity

Women's Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

sahaf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-06, 1397/02/16

Expected recruitment end date

2019-07-07, 1398/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic yogurt and conventional yogurt in blood glucose control and outcomes of pregnancy in women with gestational diabetes

Public title

The effect of probiotic yogurt and conventional yogurt in

control blood glucose and outcomes of pregnancy in women with gestational diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
pregnant women with gestational diabetes Gestational age 24-28 weeks singleton pregnancy Provision of written informed consent
Exclusion criteria:

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Random block

Blinding (investigator's opinion)
Double blinded

Blinding description
Yoghurts will be delivered from the factory without specification insertion, encoded, and distributed between the two groups of 42 who received them without any knowledge

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2018-04-10, 1397/01/21

Ethics committee reference number

IR.TBZMED.REC.1397.013

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Hemoglobin A1c

Timepoint

Before and after 8 weeks

Method of measurement

Chromatography

2

Description

Fasting Blood Sugar

Timepoint

Before and after 8 weeks

Method of measurement

spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

The subjects in the intervention group consume 300 g/d probiotic yogurt containing 106 colony of both Lactobacillus acidophilus and Bifidobacterium lactis bacteria. (Production of the Iranian milk company Pegah) for 8 weeks

Category

Treatment - Other

2

Description

Subjects in the control group consume 300g/d conventional yogurt.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

فرناز صحاف

Street address

Alzahra Hospital, South Artesh St

City

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lahroudin@gmail.com

2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Farnaz Sahaf

Street address

Taleghani hospital, Rah Ahan, Tabriz, East Azerbaijan Province

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34424882

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Rashidi

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Farnaz Sahaf

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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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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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

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