

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of probiotic yoghurt on level of blood glucose in obese and overweight pregnant women: a randomized controlled trial

Protocol summary

Summary

The aim of this randomized controlled trial is to determine the effect of probiotic yoghurt (containing Lactobacillus Acidophilus LA5 and Bifidobacterium Lactis BB12) on maternal blood glucose (primary outcome), as well as maternal and neonatal outcomes (secondary outcomes). After signing written informed consent, 130 pregnant women at about 20 weeks of gestation, covered by health center in Tabriz-Iran, with BMI \geq 25 and normal fasting blood sugar level will be recruited and allocated into two groups using stratified (overweight or obese) block randomization with allocation ratio of 1:1. Consequently numbered opaque sealed envelopes containing a paper with a unique group code will be used to conceal the allocation. The allocation sequence and envelopes will be prepared by a person not involved in data collection. Participants will be asked not to consume any probiotic products for two weeks and consume 100 g probiotic or placebo yogurt daily, identified with the group code, from 24th weeks of gestation until delivery. At 28 weeks of pregnancy, fasting blood glucose and glucose tolerance test; at 37 weeks of pregnancy, medical complications like preterm delivery, preeclampsia, as well as maternal physical activity; and following delivery, maternal (preterm delivery, preeclampsia, pregnancy weight gain and gestational diabetes) and neonatal (birth weight, hyperbilirubinemia and neonatal death) outcomes will be examined. Compliance rate, satisfaction and side effects of probiotics will also be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604013706N31**

Registration date: **2016-04-12, 1395/01/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-12, 1395/01/24

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-05-01, 1395/02/12

Expected recruitment end date

2016-11-10, 1395/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic yoghurt on level of blood glucose in obese and overweight pregnant women: a randomized controlled trial

Public title

Effect of probiotic yoghurt on level of blood glucose in obese and overweight pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20-22 weeks of pregnancy; FBS<92 mg/dl; BMI≥25; age≥ 18 years; able to read and write
Exclusion criteria: multiple pregnancy; prior history of GDM; taking any medication likely to influence metabolism of glucose (in particular metformin, glucocorticoids or immunosuppressants); medical condition associated with altered glucose metabolism (in particular Cushing's syndrome/disease and hepatic cirrhosis); known major fetal abnormality; known regular ingestion of other probiotics; smoking; antibiotic intake during current pregnancy

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **130**

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

Research deputy of Tabriz University of Medical Sciences

Street address

3rd floor, Central Building No 2, Tabriz University of Medical Science, Golgasht st., Tabriz

City

Tabriz

Postal code

Approval date

2016-03-07, 1394/12/17

Ethics committee reference number

TBZMED.REC.1394.1208

Health conditions studied

1

Description of health condition studied

impaired blood glucose

ICD-10 code

R73.0

ICD-10 code description

Abnormal glucose tolerance test

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

Before the intervention, 4 weeks after intervention

Method of measurement

laboratory assessment

2

Description

blood glucose level 1 hour after intaking 75g oral glucose

Timepoint

4 weeks after intervention

Method of measurement

laboratory assessment

3

Description

blood glucose level 2 hours after intaking 75g oral glucose

Timepoint

4 weeks after intervention

Method of measurement

laboratory assessment

Secondary outcomes

1

Description

Gestational diabetes

Timepoint

4 weeks after intervention and after delivery

Method of measurement

Laboratory Assessment

2

Description

Preeclampsia

Timepoint

37th weeks of pregnancy and after delivery

Method of measurement

clinical (blood pressure) & laboratory (proteinuria) assessment

3

Description

Preterm delivery

Timepoint

after delivery

Method of measurement

medical record assessment

4

Description

Birth weight

Timepoint

at birth, 10 days after birth

Method of measurement

medical record assessment, measurement of weight 10-12 days after birth by the researcher

5

Description

Macrosomia or Large for gestational age

Timepoint

after delivery

Method of measurement

based on birth weight

6

Description

Neonatal death

Timepoint

30 days after birth

Method of measurement

asking from participant (woman) via calling

7

Description

Neonatal bilirubine level

Timepoint

3-5 days after delivery

Method of measurement

labratory assessment

Intervention groups

1

Description

Intervention group: Probiotic yogurt (containing 109 Cfu Lactobacillus Acidophilus LA5 and Bifidobacterium Lactis BB12), 100g daily, from 24th weeks of gestation until delivery

Category

Prevention

2

Description

Control group: conventional yogurt, 100g daily, from 24th weeks of gestation until delivery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers

Full name of responsible person

Hanieh Asgharian

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz University of Medical Sciences

Full name of responsible person

Mohammad-Reza Rashidi

Street address

Research Deputy, 3rd floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht st., Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Tabriz University of Medical Sciences

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

Nursing & Midwifery Faculty, Tabriz University of medical science

Full name of responsible person

Hanieh Asgharian

Position

MSc student in midwifery

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Person responsible for scientific inquiries

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Position

PhD in Reproductive Health

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

Sakineh Mohammad-Alizadeh-Charandabi

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Email

Web page address

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