

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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, measurment 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 billirubine 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
Other areas of specialty/work
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5138947977

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

PhD in Reproductive Health

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

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Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

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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