Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of gum chewing on glycaemic control in women with gestational diabetes mellitus

Protocol summary

Study aim
Determining the effect of chewing gum on blood sugar control in women with gestational diabetes

Design
In this study, the participants were selected using convenience sampling, and were assigned into the intervention (Chewing gum) and control groups with a ratio of 1:1 by blocked randomization using Random Allocation Software (RAS) with a block size of 4.However, blinding was not possible due to the nature of the treatment modalities in the two groups, so the study used an open-label design.

Settings and conduct
Sampling will be done in an easy way among people from the research community who meet the entry criteria. The sampling location of Rouhani Babol Clinic will be covered by Babol University of Medical Sciences. By using random method with blocks of 4 (ABAB), the study subjects will be divided into two groups, A and B. Due to the intervention methods of the two groups, blinding was not possible and the study is open label and sampling is available.

Participants/Inclusion and exclusion criteria
Pregnant women 18 to 45 years old Diagnosis of GDM type A1 Between 24 and 27.6 weeks. Multiple pregnancy Overt Diabetes in before Pregnancy(such as type 1 or type 2 diabetes) History of bariatric surgery or malabsorbative bariatric surgery Chronic infectious diseases like hepatitis Dysfunction of liver and kidney (before pregnancy) Personal unwillingness to corporate the research project

Intervention groups
The intervention group will consume one type of sugar-free gum for 20 minutes before each meal for five days.For the control group, no intervention will be done during the research

Main outcome variables
En Changes in fasting blood sugar, one-hour glucose (G1hr) and two-hour glucose (G2hr) and blood sugar after each meal.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100510003902N3**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date
2023-12-29, 1402/10/08

Registrant information

Name
Farideh Mohsenzadeh

Name of organization / entity
Babol university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-11, 1402/10/21

Expected recruitment end date
2025-11-12, 1404/08/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of gum chewing on glycaemic control in women with gestational diabetes mellitus

Public title
"gum chewing in gestational diabetes mellitus"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women 18 to 45 years old Diagnosis of GDM type A1 Between 24 and 27.6 weeks.

Exclusion criteria:
Multiple pregnancy Overt Diabetes in before Pregnancy(such as type 1 or type 2 diabetes) History of bariatric surgery or malabsorbative bariatric surgery Chronic infectious diseases like hepatitis Dysfunction of liver and kidney (before pregnancy) Personal unwillingness to participate in the research project

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the participants were selected using convenience sampling, and were assigned into the intervention (Chewing gum) and control groups with a ratio of 1:1 by blocked randomization using Random Allocation Software (RAS) with a block size of 4.

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
Research ethics committee of Babol University of Medical Sciences

Street address
Mazandaran, Babol, Ganj Afroz Street, Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Approval date
2023-11-27, 1402/09/06

Ethics committee reference number
IR.MUBABOL.REC.1402.135

Health conditions studied

1

Description of health condition studied
Gestational diabetes mellitus in pregnancy

ICD-10 code
O24.41

ICD-10 code description
Gestational diabetes mellitus in pregnancy

2

Description of health condition studied
Gestational Diabetes

ICD-10 code
O24.4

ICD-10 code description
Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description
Changes in fasting blood sugar, one-hour glucose (G1hr) and two-hour glucose (G2hr) and blood sugar after each meal.

Timepoint
Record fasting blood sugar self-monitoring and one and two hours after each meal for 5 days.

Method of measurement
Glucometer

Secondary outcomes

1

Description
Adverse maternal outcomes (Preterm, pre-eclampsia, shoulder dystocia, low birth weight and macrosomia, Hospitalization in neonatal intensive care unit)

Timepoint
At the end of this study

Method of measurement
Pregnancy outcome questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will consume a type of sugar-free gum for five days for 20 minutes before each meal. Also, the participants are advised to self-monitor fasting blood sugar and one and two hours after Record and report every meal for 5 days.
Category
Treatment - Other

2

Description
Control group: No intervention will be done for the control group during the research. They will receive routine care and standard nutritional counseling. Participants will also be advised to self-monitor their fasting blood sugar and record it one and two hours after each meal for 5 days.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Farideh mohsenzadeh Ledari
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Babol University of Medical Sciences, Ganj Afrooz St, Babol, Mazandaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
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ramazan69@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Farideh Mohsenzadeh Ledari
Position
Assistant Professor of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Babol University of Medical Sciences, Ganj Afrooz St, Babol, Mazandaran
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Person responsible for scientific inquiries

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Person responsible for updating data

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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