

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 cooperate 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)

Phone

+98 11 1229 8582

Email address

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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 Afroz St,
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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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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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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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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