Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Okra powder on blood glucose levels in women with gestational diabetes mellitus under diet therapy

Protocol summary

Study aim

Determine the effect of Okra powder on blood glucose levels in women with Gestational Diabetes Mellitus under diet therapy

Design

A Phase 3 clinical trial, with a control group, no blinding, randomized allocation, 90 pregnant women with Gestational Diabetes Mellitus will be eligible. Cluster sampling and available on women with Gestational Diabetes Mellitus that Dietary therapy confirmed through tests, will be referred to Mashhad Health Centers.

Settings and conduct

Lack of blinding and sachet packaging will be done by researcher. Research units will be Women with gestational diabetes eligible referred to Mashhad health centers.At baseline, the end of the second and fourth weeks, fasting and two hours after meal blood glucose test will be done.

Participants/Inclusion and exclusion criteria

Willingness to participate, Reading and writing Literacy, Iranian and Residing in Mashhad, Having phone number, Singleton pregnancy, Gestational age between 24 and 28 weeks, Disrupting oral glucose tolerance test result at 24-28 weeks, Having Fasting Blood Glucose less than 95 mg/dL and two hours after meals less than 120 mg/dL in a test to confirm the treatment of gestational diabetes with diet, No addiction opiate, Lack of medical illness and obstetrics problems, Not attending Psychiatrists in the last six months, Lack of overt diabetes, No history of allergy to Okra and Malvacea family, Lack of Bronchitis, lack of speech and behavioral disorders.

Intervention groups

Routine care includes usual gestational diabetes diet Will be taught to both groups.The intervention group daily receives 3 grams sachets of okra powder twice a day with breakfast and lunch meals plus a glass of ordinary water(not very cold or very warm) for 4 weeks.The control group will receive routine care that includes the training usual gestational diabetes diet.

Main outcome variables

Fasting and two hours after a meal blood glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181009041296N1**
Registration date: **2018-11-11, 1397/08/20**
Registration timing: **prospective**

Last update: **2018-11-11, 1397/08/20**
Update count: **0**

Registration date

2018-11-11, 1397/08/20

Registrant information

Name

Mahla Salarfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

salarfardm961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Okra powder on blood glucose levels in women with gestational diabetes mellitus under diet therapy

Public title
The effect of Okra powder in gestational diabetes mellitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having written consent to participate in research Reading and writing literacy Iranian and residing in Mashhad Have a phone number Singleton pregnancy The gestational age between 24 and 28 weeks based on the first day of the last menstruation or the first trimester ultrasound Disrupting the test result of diagnosis of gestational diabetes at 24-28 weeks of pregnancy(Fasting blood sugar equal to or greater than 92 mg/dl or 1 hour glucose after taking 75 g glucose equal to or greater than 180 mg/dl or 2 hours glucose after taking 75 g glucose equal to or greater than 153 mg/dl) Having fasting blood glucose less than 95 mg/dl and two hours after meals less than 120 mg/dl in an experiment to confirm the treatment of gestational diabetes mellitus with a diet (after an abnormality of one of the factors tested In order to diagnose gestational diabetes) Confirmation of treatment gestational diabetes mellitus by a Gynecologist
Exclusion criteria:
Addiction Opiate and smoking Having a medical illness Having obstetrics problems Under the supervision of a Psychiatrist in the last six months and taking psychiatric drugs Having overt Diabetes Mellitus Having allergy to Okra or plant products Malvacea family Sick with Bronchitis Having speech and behavioral disorders that prevent contact with the researcher
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples are selected by clustering and then available, and Random assignment will be done by using the random numbers table at www.randomization.com in two groups (intervention and control).
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
The Ethics Committee of the Mashhad Medical Science University
Street address
Mashhad, University Street, Quraishi Building
City
Mashhad
Province
Razavi Khorasan
Postal code
91735-951
Approval date
2018-10-01, 1397/07/09
Ethics committee reference number
IR.MUMS.NURSE.REC.1397.038

Health conditions studied

1

Description of health condition studied
Gestational Diabetes Mellitus
ICD-10 code
024.4
ICD-10 code description
Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description
Fasting blood glucose
Timepoint
Baseline, 2 weeks and 4 weeks after intervention
Method of measurement
Venous blood samples

2

Description
Blood glucose two hours after a meal
Timepoint
Baseline, 2 weeks and 4 weeks after intervention
Method of measurement
Venous blood samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily intake of 3 grams of oatmeal powder twice a day with breakfast and lunch meals, with a 7-6 hour interval between meals plus a glass of ordinary water(which is not very cold or very hot) and Get routine care(The usual gestational diabetes diet) for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Get routine care (The usual gestational diabetes diet) For 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 3 of Mashhad
Full name of responsible person
Dr Brat Ali Arab Nejad
Street address
Payam street, Ershad 8, Khayyam Blvd
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Mashhad
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2

Recruitment center
Name of recruitment center
Health Center No. 2 of Mashhad
Full name of responsible person
Dr Ali Asghar Mahmoudi
Street address
Next to Vahdat Park, Vahdat Boulevard, Pnjrah down the street,
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MahmoudiA1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahla Salarfard
Street address
Faculty of Nursing and Midwifery, Ibn Sina Street
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahla Salarfard
Position
MSc Student Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Position
Professor
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Master
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Person responsible for updating data

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MSC student midwifery
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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