

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

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Payam street, Ershad 8, Khayyam Blvd

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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

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Next to Vahdat Park, Vahdat Boulevard, Pnjrah down the street,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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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