Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of Okra(Abelmoschus esculentus) Powder effects on Glucose Level, inflammatory factors (IL-6،TNF-

Protocol summary

Study aim
The effect of okra powder (Abelmoschus esculentus) on blood sugar levels, inflammatory factors (IL-6, TNF)

Design
Randomized clinical trial, 80 patients, two groups of intervention and control based on a 4-item randomized block design. The type of intervention and control is indicated by A or B.

Settings and conduct
This study is performed in Golestan University of Medical Sciences and in Gorgan city on 80 pre-diabetic patients who are divided into two groups of 40 people. The first group receives 6 capsules of 500 mg of okra powder in three meals a day for 8 weeks. . The second group receives 6 placebo capsules (cryoxymethylcellulose) in three meals a day for 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having fasting blood sugar between 100 to 125 mg per deciliter, age 30 to 55 years, Iranian citizenship, informed consent, literacy. Exclusion criteria: pregnancy and lactation in women, mental disorders that make it difficult to cooperate, concomitant diseases such as heart disease, renal failure, thyroid disease, inflammatory diseases and allergies, use of non-steroidal anti-inflammatory drugs, use steroid drugs

Intervention groups
The first group receives okra capsules. The second group receives placebo capsules (carboxymethylcellulose).

Main outcome variables
Lowering fasting blood sugar and hemoglobin A1C

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201026049154N1**
Registration date: **2020-11-08, 1399/08/18**
Registration timing: **prospective**
Last update: **2020-11-08, 1399/08/18**
Update count: **0**

Registration date
2020-11-08, 1399/08/18

Registrant information

Name
Azadreza Mansourian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3245 1653

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of Okra(Abelmoschus esculentus) Powder effects on Glucose Level, inflammatory factors (IL-6،TNF-

Public title
The effect of okra powder on blood sugar levels in pre-diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fasting blood sugar between 100 and 125 mg per deciliter

Exclusion criteria:

Pregnancy and lactation in women Existence of mental disorders at the same time that make it difficult to cooperate Concomitant diseases such as heart disease, renal failure, thyroid disease, inflammatory diseases and allergies Taking non-steroidal anti-inflammatory drugs Taking steroid drugs

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization, using Excel software by computer, 80 random numbers with frequency A and B are generated in a row. Now, the researcher places the patient in one of these two groups of patients, from 1 to 80, depending on whether it is A or B for each of the cultivars.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not know whether he is in the intervention group or placebo. The treating physician is not aware of how the patient is randomized to receive medication or placebo. The researcher and statistical consultant will not be aware of the intervention and placebo groupings.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Gorgan - Hyrkan Boulevard - Golestan University of Medical Sciences

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-10-04, 1399/07/13

Ethics committee reference number

IR.GOUMS.REC.1399.229

Health conditions studied

1

Description of health condition studied

Pre-diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce fasting blood sugar

Timepoint

At the beginning of the study and after 8 weeks of consumption of okra powder

Method of measurement

Blood sample analysis

Secondary outcomes

1

Description

HbA1C

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Blood sample analysis

2

Description

Measurement of interleukin 6 (one of the inflammatory factors) in the blood

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Blood sample analysis

3

Description

Measurement of blood TNF-

Timepoint

At the beginning of the study and after 8 weeks of

intervention

Method of measurement

Blood sample analysis

4

Description

Evaluation of miR-15a expression (one of the diabetes-related miRs)

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

With Real-time pcr method

5

Description

Expression of miR-126 expression (one of the diabetes-related miRs)

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

With Real-time pcr method

Intervention groups

1

Description

Intervention group: 500 mg okra powder capsules, two capsules, three times a day, half an hour before meals, orally for at least 8 weeks for randomized patients in this group will be prescribed. Blood samples will be taken from all patients before the intervention and after the intervention to perform tests.

Category

Treatment - Drugs

2

Description

Placebo group: 500 mg carboxymethylcellulose capsules, two capsules, three times a day, half an hour before meals, orally for at least 8 weeks for randomized patients in this group. Blood samples will be taken from all patients before the intervention and after the intervention to perform tests.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Deziani Specialized Clinic

Full name of responsible person

Dr. Fatemeh Mohammadzadeh

Street address

Beheshti Street - in front of Behesht 17

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Azadreza Mansourian

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Afsharmanesh

Position

University student

Latest degree
Master
Other areas of specialty/work
Biochemistry
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
For the sake of transparency in the research process, all data can potentially be shared after identifying individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data obtained from this research can be used by different segments of the population.
Under which criteria data/document could be used
There are no restrictions on the use of data obtained from this study.
From where data/document is obtainable
The data obtained from this study are available in information databases.
What processes are involved for a request to access data/document
The data from this study are subject to public disclosure in the database without any restrictions, so no specific request or process is required.
Comments