

# 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)

###### Phone

+98 17 3245 1653

###### Email address

azad\_r\_mansourian@goums.ac.ir

##### 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

#### City

Gorgan

#### Province

Golestan

#### Postal code

4934174515

#### Phone

+98 17 3245 2651

#### Email

msoheila66@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

##### Full name of responsible person

Azadreza Mansourian

##### Street address

Hyrkan Boulevard - Golestan University of Medical Sciences

##### City

Gorgan

##### Province

Golestan

##### Postal code

4934174515

##### Phone

+98 17 3245 1653

##### Email

azad\_r\_mansourian@yahoo.com

#### 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

**Street address**

Gorgan Jadid IV - Bahmaninejad Alley - Mahtab Building - Unit 6

**City**

Gorgan

**Province**

Golestan

**Postal code**

4913816364

**Phone**

+98 916 616 2697

**Email**

mra448@yahoo.com

Master

**Other areas of specialty/work**

Biochemistry

**Street address**

Gorgan Jadid 4 - Bahmaninejad Alley - Mahtab Building Unit 6

**City**

Gorgan

**Province**

Golestan

**Postal code**

4913816364

**Phone**

+98 916 616 2697

**Email**

mra448@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Azad Reza Mansoorian

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

**Street address**

Hyrkan Blvd.-Kelestan University of Medical Sciences - Medical School of Biochemistry

**City**

Gorgan

**Province**

Golestan

**Postal code**

4934174515

**Phone**

+98 17 3245 1653

**Email**

azad\_r\_mansourian@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Afsharmanesh

**Position**

University student

**Latest degree****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**