

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Study the effect of simultaneous consumption of a therapeutic soup and marshmallow flower tea on fasting blood glucose, body mass index and quality of life in patients with type 2 diabetes: a clinical trial

#### Protocol summary

Fasting Blood Glucose, Body Mass Index, Quality of life questionnaire score

#### Study aim

Determine the the effect of simultaneous consumption of a therapeutic soup and marshmallow flower tea on fasting blood glucose, body mass index and quality of life in patients with type 2 diabetes: a clinical trial

#### Design

This study is a Phase 2 clinical trial investigating the efficacy of a formulated soup and a marshmallow flower tea on fasting glucose in patients with type 2 diabetes mellitus. The study is performed without control group. The sample size is 60 peoples.

#### Settings and conduct

1. Patients with type 2 diabetes referring to endocrine clinic of Bahonar Hospital of Karaj are identified. 2. Patients who have a fasting blood sugar in the range of 130 - 200 meeting the other criteria of inclusion criteria, and signing a consent form to participate in the project, will be enrolled. 3. Patients perform routine tests at the beginning of the study, if adjust to inclusion criteria, their height and weight are measured, complete a quality of life questionnaire. Patients undergoing therapeutic intervention, and get to know how to use soups, marshmallow flowers and olive oil. Four weeks after participating in the intervention, measuring the parameters mentioned above are repeated again. The plan ends.

#### Participants/Inclusion and exclusion criteria

Major inclusion Criteria: FBS more than 130 and less than 200 mg/dl Major Exclusion Criteria: Having Cr. more than 3 mg/dl, Insulin Therapy, Evidence of Serious Damage to Critical Organs.

#### Intervention groups

Intervention consisted of administration of 200 cc soup as a starter before breakfast and dinner and a tea made of 1 tablespoons of marshmallow flower per cup of boiling water using after breakfast and dinner.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131115015408N3**

Registration date: **2019-08-28, 1398/06/06**

Registration timing: **prospective**

Last update: **2019-08-28, 1398/06/06**

Update count: **0**

##### Registration date

2019-08-28, 1398/06/06

##### Registrant information

##### Name

Anahita Ghourchian

##### Name of organization / entity

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3463 5198

##### Email address

dr.anahitaghurchian@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Study the effect of simultaneous consumption of a therapeutic soup and marshmallow flower tea on fasting blood glucose, body mass index and quality of life in patients with type 2 diabetes: a clinical trial

**Public title**  
Study the effect of a therapeutic soup and marshmallow flower tea on diabetes.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

FBS more than 130 & less than 200 mg/dl

**Exclusion criteria:**

Any patient who uses insulin therapy. Any patient who has Cr. more than 3 mg/dl Any patient who has red alarms mentioning serious organ damage.

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics on Research Committee of Alborz University of Medical Sciences

**Street address**

Alborz University of Medical Sciences, North Taleghani Blvd, Taleghani Square, Karaj, Iran.

**City**

karaj  
**Province**  
Alborz  
**Postal code**  
3186947535

**Approval date**

2019-06-15, 1398/03/25

**Ethics committee reference number**

IR.ABZUMS.REC.1398.055

## Health conditions studied

### 1

**Description of health condition studied**

diabetes type 2

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

**Description**

Fasting blood glucose

**Timepoint**

Before the intervention and 4 weeks after the intervention

**Method of measurement**

Blood Biochemistry Test

### 2

**Description**

Body Mass Index

**Timepoint**

Before the intervention and 4 weeks after the intervention

**Method of measurement**

Metric Scale and Digital Weighing Scale of clinic

### 3

**Description**

Quality of Life Score of the World Health Organization  
Quality of Life Questionnaire: HOQOL-BREF

**Timepoint**

Before the intervention and 4 weeks after the intervention

**Method of measurement**

World Health Organization Quality of Life Questionnaire: HOQOL-BREF

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Using 200 cc of therapeutic soup as a starter, before breakfast and dinner and a tea of 1 teaspoon of marshmallow flower put in 150 cc boiled water after breakfast and dinner. Duration of intervention is 4 weeks.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Bahonar Hospital, Emam Ali Polyclinic, Endocrinology Clinic

#### Full name of responsible person

Anahita Ghourchian

#### Street address

Valiasr Blvd., Azimiyeh Road, Karaj, Alborz Provincane, Iran Valiasr Blvd., Azimiyeh Road, Karaj, Alborz Provincane, Iran Valiasr Blvd., Azimiyeh Road, Karaj, Alborz Provincane, Iran

#### City

Karaj

#### Province

Alborz

#### Postal code

3154686695

#### Phone

+98 26 3254 6372

#### Fax

+98 26 3254 7128

#### Email

EMAMALI@abzums.ac.ir

#### Web page address

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Karaj University of Medical Sciences

#### Full name of responsible person

Mohammad Noorisepehr

#### Street address

Deputy of research and technology, Shahid Saffarian Ave., Shahid Shams Blv., Golshahr

#### City

Karaj

#### Province

Alborz

#### Postal code

3198764653

#### Phone

+98 26 3464 4083

#### Fax

#### Email

Research@abzums.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Karaj 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

Karaj University of Medical Sciences

#### Full name of responsible person

Anahita Ghourchian

#### Position

Non-Academic Specialist Physician

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Traditional Medicine

#### Street address

Medical School, West Bouali Ave., Moazzen Blvd., Nobovvat Square, Karaj, Iran

#### City

Karaj

#### Province

Alborz

#### Postal code

3139916144

#### Phone

+98 26 3428 7425

#### Email

anahitaghourchian@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Karaj University of Medical Sciences

#### Full name of responsible person

Anahita Ghourchian

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Non-Academic Specialist Physician

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**Person responsible for updating data**

**Contact**

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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**

All participant data can be shared after being  
unidentifiable.

**When the data will become available and for how long**

Accessing starts 6 months after printing the results.

**To whom data/document is available**

The general public

**Under which criteria data/document could be used**

Allowed for using in studies.

**From where data/document is obtainable**

Anahita Ghourchian, Medical School of Alborz University  
of Medical Sciences.

**What processes are involved for a request to access data/document**

Send request to project manager by email. Within 1  
week will receive the necessary items.

**Comments**