

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

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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

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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

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3198764653

Phone

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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

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

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anahitaghourchian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Anahita Ghourchian

Position

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Person responsible for updating data

Contact

Name of organization / entity

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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