

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study the combined effect of the Spinach and Okra on sex hormones (LH, FSH, Testosterone, DHT, and DHEA) of obese men and women with type II diabetes

Protocol summary

Study aim

Study the combined effect of the Spinach and Okra on Sex hormones (LH, FSH, Testosterone, DHT, and DHEA) of obese men and women with type II diabetes

Design

This study is a non-blinded clinical trial. The study population will include all patients referred to the diabetes ward of Taleghani hospital of Kermanshah. 50 eligible patients will be selected conveniently and randomly will be assigned to two intervention groups.

Settings and conduct

This study which will be conducted in Taleghni hospital of Kermanshah is non-blinded one. Blood samples will be taken at baseline and 3 months after completion of the study, and sex hormone levels will be measured before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with type 2 diabetes; People over 30 years old; People with Kidney Failure Disease (CKD) Exclusion criteria: People with type 1 diabetes; Pregnant women

Intervention groups

The intervention group will receive 2 grams of freshly dried spinach powder and 4 grams of fresh okra eggs before breakfast. The control group will receive no intervention

Main outcome variables

Sex hormones

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N128**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the combined effect of the Spinach and Okra on sex hormones (LH, FSH, Testosterone, DHT, and DHEA) of obese men and women with type II diabetes

Public title

Study the combined effect of the Spinach and Okra on sex hormones of obese men and women with type II

diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 People with type 2 diabetes People over 30 years old BMI higher than 29.9
Exclusion criteria:
 People with Kidney Failure Disease (CKD) People with type 1 diabetes pregnant women

Age
From 30 years old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
Individual randomization method via code reception by random number table

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
 Ethics committee of Kermanshah University of Medical Sciences
Street address
 Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
 Kermanshah
Province
 Kermanshah
Postal code
 6715847141
Approval date
 2019-08-27, 1398/06/05
Ethics committee reference number
 ir.kums.rec.1398.621

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Sex hormones

Timepoint

At the beginning of the study and three months after the end of the study

Method of measurement

Using blood tests

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive 2 grams of freshly dried spinach powder and 4 grams of fresh okra eggs before breakfast.

Category

Treatment - Other

2

Description

The control group will receive no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Mohamad Rasoul Mohammadi

Street address

Diabetes Research Center, Taleghani Hospital, Shahid Beheshti Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Phone

+98 83 3836 2014

Email

mohamadrasoul23.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
Beheshti

City

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Phone

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Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohamad Rasoul Mohammadi

Position

PhD student in medicine

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Parastar Boulevard

City

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Postal code

6715847141

Phone

+98 83 3427 4618

Email

mohamadrasoul23.m@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Mehrali Rahimi

Position

Member of Kermanshah University of Medical
Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology & Metabolism

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Diabetes Research Center, Taleghani Hospital, Shahid
Beheshti Blvd.

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Email

mjavadra@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mohamad Rasoul Mohammadi

Position

PhD student in medicine

Latest degree

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Phone

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Email

mohamadrasoul23.m@gmail.com

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

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 month

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments