

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of okra (*Abelmoschus esculentus*) fruit dried extract on several genes expression, serum metabolic, oxidative stress, and autophagy- related parameters, anthropometric indices, appetite, and kidney function in diabetic nephropathic patients

Protocol summary

Study aim

To determine the effects of okra (*Abelmoschus esculentus*) fruit dried extract on several genes expression, serum metabolic, oxidative stress, and autophagy- related parameters, anthropometric indices, appetite, and kidney function in diabetic nephropathic patients

Design

A randomized, controlled, triple-blind, clinical trial with 60 patients

Settings and conduct

Participants in this study will be selected from patients with diabetic nephropathy referred to Tabriz Imam Reza Hospital, after being confirmed by a specialist. Patients in this study will be randomly divided into placebo and supplement groups. All stages of the study as well as the interventions and follow-ups will be done in the Faculty of Nutrition, Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 40 to 70 years, BMI ≥ 25 kg/m² and BMI < 38 kg/m², Excretion of protein greater than 0.3g in 24-hour urine for more than 3 months. Willingness to participate in the study. B) Exclusion criteria: Weekly consumption of okra over the past three months, Pregnancy and lactation, Other Kidney Diseases, Liver Disease, Thyroid disorders and Inflammatory Diseases, Cancer, NSAIDS consumption and so on, energy intake less than 800 or more than 4200 kcal per day based on a three-day food record questionnaire, Following unusual weight loss regimens (like water treatment, single food eating, Canadian diet, etc.) 3 months before the enrollment, People taking warfarin or other anti-coagulants. Cardiovascular Disease (Stages 2 and 3), Uncontrolled diabetes (HbA1c > 8).

Intervention groups

Supplement group (Okra recipient), placebo group

(Carboxymethyl cellulose recipient)

Main outcome variables

metabolic, antioxidant, kidney, inflammatory, and autophagy-related parameters

General information

Reason for update

to add some new parameters to the project

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006652N3**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**

Update count: **2**

Registration date

2020-04-16, 1399/01/28

Registrant information

Name

Maryam Saghafi asl

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01
Expected recruitment end date
2020-12-21, 1399/10/01
Actual recruitment start date
2020-06-21, 1399/04/01
Actual recruitment end date
2021-01-04, 1399/10/15
Trial completion date
2021-09-23, 1400/07/01

Scientific title

The effects of okra (*Abelmoschus esculentus*) fruit dried extract on several genes expression, serum metabolic, oxidative stress, and autophagy- related parameters, anthropometric indices, appetite, and kidney function in diabetic nephropathic patients

Public title

The effects of okra (*Abelmoschus esculentus*) fruit dried extract on kidney function in diabetic nephropathic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI ≥ 25 kg / m² and BMI < 38 kg / m² Age: 40 to 70 years Excretion of protein greater than 0.3 g in 24-hour urine for more than 3 months Willingness to participate in the study

Exclusion criteria:

Weekly consumption of okra over the past three months Pregnancy and lactation Other Kidney Diseases, Liver Disease, Thyroid disorders and Inflammatory Diseases, Cancer, NSAIDS consumption and so on. Energy intake less than 800 or more than 4,200 kcal per day based on a three-day feed record questionnaire Following unusual weight-loss regimens 3 months before the enrollment (like water treatment, single food eating, Canadian diet, ...) People taking warfarin or other anti-coagulants Cardiovascular Disease (Stages 2 and 3) Uncontrolled diabetes mellitus (HbA1c >8)

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **25**

The sample size was estimated based on blood glucose, using mean and standard deviation obtained from yet unpublished data of Ghaffari et al. with 95% confidence ($\alpha = 0.05$) and 80% power ($\beta = 20\%$). About 23 patients were estimated to be in each group; however, 25 patients would be recruited in each group, considering the

probable loss. Each group will consist of patients with diabetic nephropathy whom will randomly receive either dried extract of Okra or placebo (carboxymethyl cellulose).

Actual sample size reached: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

At the beginning of the study, the eligibility criteria including BMI, age, and gender will be matched by blocking method. Sixty subjects with diabetic nephropathy will be randomly assigned into either intervention group (okra recipient) or control group (carboxymethyl cellulose recipient), using RAS software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After randomization, the dried extract of okra will be allocated into the supplement group and carboxymethyl cellulose will be given to the placebo group as a capsule. The capsules will be filled without the involvement of the researchers and will be numbered as 1 and 2 codes. The nutrition expert will introduce the capsules with either code 1 or code 2. Until the release of the study results, neither the patients nor the researchers or doctors and statistician will not be informed of the allocated codes. The numbers will be decoded at the study end-point. Therefore, the study will be triple-blinded.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Third Floor, Central Building (2), Tabriz University of Medical Sciences, Golghasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2019-11-11, 1398/08/20

Ethics committee reference number

IR.TBZMED.REC.1398.806

Health conditions studied

1

Description of health condition studied

Diabetic Nephropathy

ICD-10 code

E08.21

ICD-10 code description

diabetic nephropathy

Primary outcomes

1

Description

fasting blood glucose

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

enzymatic colorimetric

2

Description

HBA1c

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

chromatography

3

Description

serum insulin

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

ELISA kit

4

Description

homeostatic model assessment of insulin resistance

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

calculating with formula

5

Description

LDL-C

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

calculating with formula

6

Description

HDL-C

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

7

Description

total cholesterol

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

8

Description

triglyceride

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

9

Description

serum Albumin

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

10

Description

serum creatinine

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

11

Description

Blood urea nitrogen

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

12

Description

Urine Total Protein

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

13

Description

urine creatinine

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

14**Description**

serum malondialdehyde

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

15**Description**

serum glutathione peroxidase

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

16**Description**

advanced glycation end products

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

17**Description**

Soluble receptor for advanced glycation end products

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

laboratory kit

18**Description**

serum nitric oxide

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

ELISA

19**Description**

hs-CRP

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

ELISA

20**Description**

gene expression of interleukin-1beta

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

21**Description**

gene expression of glucagon like peptide

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

22**Description**

serum dipeptidyl peptidase-4

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

ELISA

23**Description**

gene expression of receptor advanced glycation end products

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

24**Description**

gene expression of ICAM

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

25**Description**

Peroxisome proliferator-activated receptor-γ

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

26**Description**

Peroxisome proliferator-activated receptor-α

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

27**Description**

gene expression of NF-E2-related factor 2 (NRF-2)

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

28

Description

gene expression of Pentraxin-3

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

29

Description

gene expression of Transforming growth factor beta

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

30

Description

serum level of mTOR

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Elisa

31

Description

serum level of SIRT-1

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Elisa

32

Description

serum level of Beclin-1

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Elisa

33

Description

gene expression of Autophagy Related gene 5

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

34

Description

gene expression of LC-3

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

35

Description

gene expression of Unc-51 Like Autophagy Activating Kinase 1

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

36

Description

gene expression of Beclin-1

Timepoint

at baseline and 10 weeks after intervention

Method of measurement

Real time - PCR

Secondary outcomes

1

Description

weight

Timepoint

At baseline and three months after

Method of measurement

Digital Scales

2

Description

Waist

Timepoint

At baseline and three months after

Method of measurement

Non-elastic meter

3

Description

blood pressure

Timepoint

At baseline and three months after

Method of measurement

Blood pressure Monitor

4

Description

body fat percent

Timepoint

At baseline and three months after

Method of measurement

body composition devise

5

Description

lean body mass percent

Timepoint

At baseline and three months after

Method of measurement

body composition devise

6**Description**

appetite

Timepoint

At baseline and three months after

Method of measurement

questionnaire

Intervention groups**1****Description**

Control group: In this study, patients in the placebo group will receive one capsule containing 125 mg carboxymethyl cellulose for 10 weeks. Diet evaluation will be performed using a 24-hour three-day food record questionnaire (including two mid-week days and one weekend day) at baseline and at the end of the tenth week. Patients will be instructed to refrain from any change in diet, physical activity, type or dosage of their medications during the study. Otherwise, they will be excluded from the study. Patients will be followed up every two weeks by phone call so as to control the use of the placebo and prevent any drop-out. Patients will also be asked to bring the bottle of remaining capsules with them at the second visit. If a patient consumes less than 90% of the capsules, he/ she will be excluded from the study.

Category

Placebo

2**Description**

Intervention group: In this study, patients in the intervention group will receive one capsule containing 125 mg dried okra extract for 10 weeks. Diet evaluation will be performed using a 24-hour three-day food record questionnaire (including two mid-week days and one weekend day) at baseline and at the end of the tenth week. Patients will be instructed to refrain from any change in diet, physical activity, type or dosage of their medications during the study. Otherwise, they will be excluded from the study. Patients will be followed up every two weeks by phone call so as to control the use of the supplements and prevent any drop-out. Patients will also be asked to bring the bottle of remaining capsules with them at the second visit. If a patient consumes less than 90% of the capsules, he/ she will be excluded from the study.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Dr. Vahideh Sadra

Street address

Golgasht, Next to Tabriz University, Imam Reza Hospital

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2**Recruitment center****Name of recruitment center**

Tabriz Sheikhoraees clinic

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Nutrition Research Center, Tabriz University of medical Sciences, Tabriz, Iran

Full name of responsible person

Dr. Alireza Ostadrahimi

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz 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

2

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Samiee

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Research Vice-chancellor, Tabriz University of Medical Sciences, University street, Tabriz, Iran

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
omid nikpayam

Position
Ph.D candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associate Professor

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Nutrition

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person

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Position

Msc student in Nutrition science

Latest degree

Bachelor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Publish results

When the data will become available and for how long

After finishing and publishing the project article

To whom data/document is available

University researchers

Under which criteria data/document could be used

With permission from Project Researcher and Project
Supporting Organization - Nutrition Research Center and
Research Deputy

From where data/document is obtainable

Dr Maryam Saghafi Asl-Tabriz University of Medical
Sciences, School of Nutrition and Nutrition, Email:
Saghafiaslm@gmail.com

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

The recipient can send an application to the study
subject via email.

Comments