Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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

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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 <38kg / 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 (α = 0.05) and 80% power (β = 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 glitathione 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
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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
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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
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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

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Person responsible for updating data

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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