Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Hibiscus sabdariffa L. extract and thiazide on albuminuria in patients with type 2 diabetes

Protocol summary

Study aim
Comparing the efficacy of Hibiscus sabdariffa with thiazide on reducing the amount of albuminuria in patients with type 2 diabetes

Design
Clinical trial with two intervention groups, with parallel groups, double-blind, randomized block design, phase 2 on 128 patients.

Settings and conduct
Each patient in the first group will receive 25 mg of hydrochlorothiazide tablets and 40 mg of valsartan tablets every 12 hours, and in the second group, 420 mg of hibiscus tablets every 12 hours in the morning and at night and 40 mg of valsartan every 12 hours in the two groups with similar packaging. and the patients and the doctor evaluating the interventions do not know the type of medicine received. At the beginning of the study, the patients were randomly placed in the above two groups; GFR, fasting blood sugar, HgA1C, 24-hour urine protein and albumin, creatinine, TG CHOLESTEROL LDL HDL and blood pressure before and after the intervention (within a period of 3 months) are checked and compared. In addition, they will be monitored weekly during the first month and over the phone by the doctor and the project manager in terms of possible side effects.

Participants/Inclusion and exclusion criteria
Age 40 to 70 years A patient diagnosed with type 2 diabetes Blood pressure higher than 130.80 mm Hg Follow up and continue the treatment of the patient and visit the clinic

Intervention groups
Group A: group receiving ARBs (angiotensin II receptor blockers) + thiazide (hydrochlorthiazide 25 mg daily) Group B: group receiving ARBs + hibiscus (Hyporex-B tablets 420 mg twice a day)

Main outcome variables
albuminuria; GFR, blood pressure and lipid profile and FBS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200522047538N1**
Registration date: **2022-09-26, 1401/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-26, 1401/07/04**
Update count: **0**

Registration date
2022-09-26, 1401/07/04

Registrant information
Name
Maryam Kiani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of Hibiscus sabdariffa L. extract and thiazide on albuminuria in patients with type 2 diabetes

Public title
Comparison of the effect of Hibiscus sabdariffa L. extract and thiazide on albuminuria in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
40 to 70 years old2 Man or Non-pregnant woman Provide conscious written and verbal consent The patient should be admitted to the clinic with a diagnosis of type 2 diabetes confirmed Blood pressure above 130/80 mm Hg The person is willing and able to follow the study instructions and go to the clinic for a visit.
Exclusion criteria:
Allergic to the plant Normal blood pressure (mm HgSBP ≤ 120; DBP ≤ 80 mm Hg) Stage two and above Patients with renal failure, coronary artery disease, heart failure .Pregnancy Any metabolic or malabsorption disease that may interfere with the absorption of hibiscus (such as celiac disease, chronic pancreatitis, etc.). Taking psychiatric medications (mood stabilizer, antidepressant, anti-anxiety or antipsychotic)
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be assigned to the experimental and control groups using the randomized block method. For random allocation using blocks of 4, first by throwing 32 regular hexagons, a random sequence of 32 blocks of 4 will be generated from among the following blocks: AABB-ABAB-ABBA-BAAB-BABA-BBAA
Blinding (investigator's opinion)
Double blinded
Blinding description
All patients and doctors evaluating the interventions designed in the study or the outcomes after the intervention (internal medicine assistant and nephrology and blood pressure subspecialist) will not know about the group in which the patient is examined. All interventions in both groups will be designed similarly and the procedure will be the same on all samples in all groups. The drugs used will also be supplied in the same form and packaging so that it is not possible to identify the study group during the study process.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences
Street address
Vice President of Research, Golestan University of Medical Sciences, the beginning of Shast Kala Road, Hirkan Blvd., Gorgan
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Province
Golestan
Postal code
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Approval date
2022-08-21, 1401/05/30
Ethics committee reference number
IR.GOUMS.REC.1401.264

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E08.2
ICD-10 code description
Diabetes mellitus due to underlying condition with kidney complications

Primary outcomes

1

Description
urinary albumin
Timepoint
Albuminuria before the intervention and 3 months later
Method of measurement
Using a 24-hour urine collection test and examining the amount of protein and albumin excretion

Secondary outcomes

1

Description

blood pressure

Timepoint

Blood pressure with a sphygmomanometer before the start of the intervention and three consecutive weeks after the start of the intervention and after the end of the intervention

Method of measurement

Blood pressure measurement is performed by an experienced and trained technician who is unaware of the intervention, in a blinded manner. According to the Kaplan protocol, the blood pressure of the patients after at least 5 minutes of rest in a sitting position for three consecutive weeks at a certain hour by It is measured by an experienced and trained technician. For this measurement, Richter's Nova model desktop mercury pressure gauge is used.

Intervention groups

1

Description

Intervention group: 25 mg hydrochlorothiazide tablets daily and 40 mg valsartan tablets every 12 hours

Category

Treatment - Drugs

2

Description

Intervention group: 420 mg hibiscus tablet every 12 hours morning and night

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayad Shirazi Hospital, Gorgan

Full name of responsible person

Mr. Dr. Saeed Amir Khanlou

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Shahid Sayad Shirazi Hospital, Shahid Sayad Shirazi Boulevard, Bahnar Square, Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

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?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr.Maryam Kiani

Position

Specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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
No - There is not 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
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
There are no special conditions.

From where data/document is obtainable
Dr. Maryam Kiani Phone number :00989113778569 Email: kiani.m94@gmail.com

What processes are involved for a request to access data/document
The applicant should provide his / her study file and the purpose of receiving the data in the form of an email with his / her research file (research plan), then after 3 months the file will be provided to the person

Comments