Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Hibiscus sabdariffa L. extract and thiazide on treatment of hypertension in patients with mild chronic kidney disease

Protocol summary

Study aim

Comparison of blood pressure changes in Hibiscus sabdariffa and thiazide groups in patients with chronic renal failure Sub-objectives: Comparison of albuminuria, proteinuria, hyperlipidemia and changes in sodium and potassium electrolytes and the progression of renal failure in the two groups of Hibiscus sabdariffa and thiazide in patients with chronic renal failure

Design

A clinical trial study with a control group, community-based and pragmatic, with parallel groups, double-blind, randomized by randomized block method, phase 3 on 64 patients

Settings and conduct

In the field of changes in blood pressure following the use of drugs in patients with hypertension, in the nephrology clinic of Sayad Shirazi Hospital, double-blind (patient and physician evaluating)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 18 and 70 years 2. Consent to participate in the study 3. A patient with clinical signs of hypertension with mild renal failure 4. Abnormal blood pressure (=> 130/80 according to AHA criteria) Exclusion criteria: 1- Allergy to herbal medicines 3- Patients with diabetes mellitus, severe renal failure, coronary artery disease, heart failure, malignant hypertension [BP ≥ 180/110], etc.) 4 - changing of antihypertensive drugs 5- Systolic blood pressure < 100 or => 160/100 7- Pregnancy 8. Any metabolic or malabsorption disease . 9- Use of psychiatric drugs

Intervention groups

1 .Valsartan + thiazide 2. Valsartan + hibiscus

Main outcome variables

During the course of the study, none of the participants will be deprived of the standard treatment required by each volunteer. If blood pressure drops or rises during treatment, patients will be excluded from the study and return to their original treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210926052600N1**
Registration date: **2021-12-22, 1400/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-22, 1400/10/01**
Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name

Behdad Ḏehkhoda

Name of organization / entity

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

2021-09-21, 1400/06/30

Actual recruitment end date

2022-03-21, 1401/01/01

Trial completion date

2023-02-19, 1401/11/30

Scientific title

Comparison of the effect of Hibiscus sabdariffa L. extract and thiazide on treatment of hypertension in patients with mild chronic kidney disease

Public title

Comparison of the effect of Hibiscus sabdariffa L. extract and thiazide on treatment of hypertension in patients with mild chronic kidney disease : A randomized controlled clinical trial: double blinded

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Non-pregnant man or woman 18 to 70 years old 2. Consent to participate in the study 3. A patient with confirmed clinical signs of hypertension with mild renal failure 4. Abnormal blood pressure (=> 130/80 according to AHA criteria) 5. Patient follow-up

Exclusion criteria:

1- Allergy to the plant 2- Normal blood pressure (mm HgSBP ≤ 120; DBP ≤ 80 mm Hg) / blood pressure below 100 and blood pressure => 160/100 3- Patients with diabetes mellitus, severe renal failure, coronary artery disease, heart failure, malignant hypertension [BP ≥ 180/110], etc.) 4- Study of changing antihypertensive drugs in patients 5- Systolic blood pressure below 100 during the study 6- Pregnancy 7. Any metabolic or malabsorption disease that may interfere with the absorption of hibiscus (such as celiac disease, chronic pancreatitis, etc.). 8- Use of psychiatric drugs (mood stabilizer, anti-depressant, anti-anxiety or anti-psychotic

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to experimental and control groups using the random block method. To perform randomization using quadruple blocks, first by throwing 16 regular hexagons 16 times, a random sequence of 16 quadruple blocks will be generated from the following blocks: AABB-ABAB-ABBA-BAAB-BABA-BBAA In the sequence, there will be 32 of each letter A and B. According to the above block, 64 envelopes will be prepared and in each envelope, the letter A or B will be placed and will be numbered from 1 to 64. The person delivering the envelopes to the patients does not know the letters inside. Randomization is done by a statistics and methodology consultant who does not have access to patients and only he knows what is in each envelope. Patients who received the letter A will be in the intervention group and patients who received the letter B will be in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind, so that all patients and physicians evaluating the interventions designed in the study or the consequences after the intervention (assistant of internal medicine and nephrology and hypertension) will not be aware of the patient grouping. The drugs used will be available in similar form and packaging so that it is not possible for anyone 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 Chancellor for Research and Technology, Golestan University of Medical Sciences, at the beginning of Shast Kola Road, Hyrkan Street

City

Gorgan

Province

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Postal code

4934174515

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.Goums.Rec.1400.229

Health conditions studied

1

Description of health condition studied

Patients with hypertension with mild renal failer

ICD-10 code

I12

ICD-10 code description

Hypertensive chronic kidney disease

Primary outcomes

1

Description

Patients' blood pressure changes,, albuminuria and proteinuria

Timepoint

Blood pressure at the beginning and 3 months after the intervention

Method of measurement

Based on laboratory Examination

2

Description

electrolytes

Timepoint

Electrolytes at the beginning and 3 months after the start of the intervention

Method of measurement

Based on laboratory Examination

3

Description

Albuminuria and proteinuria

Timepoint

albuminuria, proteinuria, GFR according to MDRD formula

Method of measurement

Based on laboratory Examination

Secondary outcomes

empty

Intervention groups

1

Description

In the first group, 25 mg of hydrochlorothiazide tablets and 40 mg of valsartan tablets daily every 12 hours for 3 months

Category

Treatment - Drugs

2

Description

Control group: Control group: Group 2: 420 mg hibiscus tablets every 12 hours and 40 mg valsartan every 12 hours for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayad Shirazi Hospital, Gorgan

Full name of responsible person

Dr. Saeid Amirkhanloo

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Sayad Shirazi Hospital, Sayad Shirazi Boulevard, Bahonar Square, Gorgan

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Sponsors / Funding sources

1

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Name of organization / entity

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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

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Position

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available