Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the pharmacological effect of jujube fruit hydroalcoholic extract (Ziziphus jujuba Mill.) in patients with primary hypertension: a pilot study

Protocol summary

Study aim
Determination of the pharmacological effect of jujube fruit in primary hypertension

Design
Clinical trial with control group, parallel, randomized, phase 0, 40 patients.

Settings and conduct
Demographic information and patient history will be recorded at the beginning of the study. In the clinic of Sayad Shirazi Medical Sciences Educational Center of Golestan, both arms will be measured with Richter's Nova model mercury barometer.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 120 mmHg < blood pressure <160 mmHg (Pre- and stage 1 hypertension) Age over 18, female or male Written consent Exclusion criteria: Other heart diseases; Secondary hypertension; Serum Potassium > 5.5 mmol/L or < 3.5 mmol/L; Doubling serum creatinine in the last 6 months; Severe complications of diabetes or serious macro vascular events within 6 months (for example, cerebral hemorrhage, cerebral infarction, or acute myocardial infarction); Recent infection in the last 4 weeks; Primary or secondary kidney disease (e.g., immunoglobulin A nephropathy, membranous nephropathy, or lupus nephritis); Any cancer and malignancy; Severe mental disorder; Pregnant or lactating women or women who are planning to become pregnant or women who are not using appropriate contraceptive methods; Drug or jujube allergies; Participate in other clinical trials; Use of other herbal medicines to control the symptoms of the present disease; History of smoking drugs; Other conditions that the researchers considered in appropriate in this clinical study

Intervention groups
control group: routine drug plus placebo of Ziziphus jujuba group 1: routine drug plus Ziziphus jujuba (7 g/day) group 2: routine drug plus Ziziphus jujuba (14 g/day) group 3: routine drug plus Ziziphus jujuba (28 g/day) Study period in groups is 4 weeks.

Main outcome variables
hypertension

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200506047325N2**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date
2023-05-31, 1402/03/10

Registrant information

Name
Ayesheh Enayati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3245 1434

Email address
enayati_phyto@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the pharmacological effect of jujube fruit hydroalcoholic extract (Ziziphus jujuba Mill.) in patients with primary hypertension: a pilot study

Public title
Investigating the effective concentration of jujube fruit in primary hypertension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
mmHg160 < blood pressure < mmHg 120 (Pre- and stage 1 hypertension) Voluntary participation in this clinical study and written consent
Exclusion criteria:
Other heart diseases Secondary hypertension Serum potassium> 5.5 mmol / L or <3.5mmol / L Doubling of serum creatinine in the last 6 months Severe complications of diabetes or seriousmacrovascular events within 6 months (e.g., cerebral hemorrhage, cerebral infarction, or acute myocardial infarction) Recent infection in the last 4 weeks Primary or secondary kidney disease (e.g., IgA nephropathy, membranous nephropathy, or lupus nephritis) Any cancer and malignancy Severe mental disorder Pregnant or lactating women or women who are planning to become pregnant or women who arenot using appropriate contraceptive methods Participate in other clinical trials Drug or jujube allergies Use of other herbal medicines to control the symptoms of the present disease History of smoking, drugs Other conditions that the researchers considered in appropriate in this clinical study
Age
From **18 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The random assignment list will be computer generated with a 1:1 allocation, stratified by recruitment site, using random block size of four. Using concealed in sequentially numbered, sealed, opaque envelopes (SNOSE), participants will enter the blocks in such a way that an equal number of each assigned group. Allocation will be done by randomly selecting one of the arrangements and assigning the next part of the participants to the study groups according to the specified sequence. And kept by the hospital pharmacist of the center.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
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
Shastkola Road
City
gorgan
Province
Golestan
Postal code
4934174515
Approval date
2023-04-25, 1402/02/05
Ethics committee reference number
IR.GOUMS.REC.1402.028

Health conditions studied

1

Description of health condition studied
Essential (primary) hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Hypertension
Timepoint
Round 0: starting the study and receiving medication (face-to-face consultation)Round 1: 2 weeks after receiving the drug (telephone)The third round: the fourth week, the end of the medical treatment period (face-to-face consultation)
Method of measurement
Mercury barometer

Secondary outcomes

1

Description
Change in serum creatinine (SCr)
Timepoint
At the beginning of the study and at the end of the drug treatment period (4th week)
Method of measurement
Blood and urine tests

2

Description
eGFR
Timepoint
At the beginning of the study and at the end of the drug treatment period (4th week)
Method of measurement
Blood and urine tests

3

Description
Serum Albumin
Timepoint
At the beginning of the study and at the end of the drug treatment period (4th week)
Method of measurement
Blood and urine tests

4

Description
Lipid profiles
Timepoint
At the beginning of the study and at the end of the drug treatment period (4th week)
Method of measurement
Blood tests

5

Description
ECG
Timepoint
At the beginning of the study and at the end of the drug treatment period (4th week)
Method of measurement
Electrocardiograph

6

Description
Liver enzymes
Timepoint
At the beginning of the study and at the end of the drug treatment period (4th week)
Method of measurement
Blood tests

Intervention groups

1

Description
Intervention group: recipient of routine drug treatment + Ziziphus jujuba fruit extract (7 g/day) for 4 weeks
Category
Treatment - Drugs

2

Description
Intervention group: recipient of routine drug treatment + Ziziphus jujuba fruit extract (14 g/day) for 4 weeks
Category
Treatment - Drugs

3

Description
Intervention group: recipient of routine drug treatment + Ziziphus jujuba fruit extract (28 g/day) for 4 weeks
Category
Treatment - Drugs

4

Description
Control group: receiving routine medical treatment + placebo Ziziphus jujuba fruit extract for 4 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ischemic Disorders Research Center,Golestan University of Medical Sciences
Full name of responsible person
Dr. Aref Salehi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges Beigom Mirbehbahani
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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
Aref Salehi
Position
Assistant Professor of Cardiology
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable