Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Investigation of antihypertensive effect of antioxidant enriched Ziziphus jujuba fruit extract in patients with primary hypertension: A randomized, double-blind, placebo controlled clinical trial

Protocol summary

Study aim
Determination of antihypertensive effect of antioxidant enriched extract of Ziziphus jujuba fruit in patients with primary hypertension

Design
Two arm parallel groups randomized trial with blinded postoperative care and outcome assessment

Settings and conduct
Patients with primary hypertension (hypertension and stage 1) referred to the clinic of Sayad Shirazi Medical Center of Golestan Medical Sciences over 18 years of age, randomly, double-blind, placebo-controlled study will be included in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: mmHg120 <blood pressure <mmHg 160 (Pre- and stage 1 hypertension) Age over 18, female or male Voluntary participation in this clinical study and submission of written consent Exclusion criteria: Other heart diseases Secondary blood pressure Serum potassium> 5.5 mmol / L or <3.5 mmol / L double Serum creatinine in the last 6 months Severe complications of diabetes or serious macrovascular 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 are not using appropriate contraceptive methods Participate in other clinical trials Drug allergies 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 inappropriate in this clinical study

Intervention groups
Control group: routine drug treatment + placebo for 12 weeks Intervention group: routine drug treatment + extract of Ziziphus jujuba fruit for 12 weeks

Main outcome variables
Blood pressure

General information

Reason for update
Change of sponsors of financial resources and delay in sampling time.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200506047325N1**
Registration date: **2021-11-18, 1400/08/27**
Registration timing: **prospective**

Last update: **2023-02-27, 1401/12/08**
Update count: **1**

Registration date
2021-11-18, 1400/08/27

Registrant information

Name
Ayesheh Enayati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3245 1434

Email address
enayati_phyto@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of antihypertensive effect of antioxidant enriched Ziziphus jujuba fruit extract in patients with primary hypertension: A randomized, double-blind, placebo controlled clinical trial

Public title

Evaluation of anti-hypertensive effect of jujube fruit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

120 mmHg < blood pressure < mmHg 160 (Pre- and stage 1 hypertension) Age over 18, female or male Voluntary participation and written consent

Exclusion criteria:

Other heart diseases Secondary blood pressure Serum Potassium > 5.5 mmol/L or < 3.5 mmol/L double serum creatinine in the last 6 months Severe complications of diabetes or serious macrovascular 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., 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 are not using appropriate contraceptive methods Drug allergies 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 inappropriate in this clinical study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

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)

Double blinded

Blinding description

To maintain blindness in patients, the drug and placebo are the same in shape and appearance; Also, the evaluator is not aware of the type of drugs in the intervention groups, so that multi-digit numerical codes are written on the drug packages that only the main person in charge of the research is aware of.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Golestan University of Medical Sciences

Street address

Shastkola Road

City

Gorgan

Province

Golestan

Postal code

14395-477

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.GOUMS.REC.1400.273

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

blood pressure

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

1

Description

SCr

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Blood and urine tests

2

Description

eGFR

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Blood and urine tests

3

Description

Serum Albumin

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Blood and urine tests

4

Description

Serum Potassium

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Blood and urine tests

5

Description

EGC

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Electrocardiograph

6

Description

Liver enzymes

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Blood tests

7

Description

ACE2 enzyme

Timepoint

0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)

Method of measurement

Bloodtests

8

Description
Serum Nitric oxide
Timepoint
0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)
Method of measurement
Blood tests

9

Description
Lipid profiles
Timepoint
0: Start studying and receiving medication (in person),1: 2 weeks after receiving stage 1 medication (in person), 3: Week 8 End of stage 2 drug treatment course (in person), 4: Week 12 after receiving the drug stage 3 (face-to-face visit), 5: First follow-up - 2 weeks after receiving the drug (week 14) (telephone follow-up), 6: Second follow-up - 4 weeks after receiving the drug (week 16) (face-to-face visit)
Method of measurement
Blood tests

10

Description
diet
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Diet with 24Recall checklist

Intervention groups

1

Description
Intervention group: Receiving routine drug treatment + enriched antioxidant extract of Ziziphus jujuba fruit for 12 weeks (3 months). Patients will be evaluated for symptoms at 14 weeks and 16 weeks after the end of the study.
Category
Treatment - Drugs

2

Description
Control group: Receiving routine drugs+ placebo for 12 weeks (3 months)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ischemic Disorders Research Center, Golestan University of Medical Sciences
Full name of responsible person
Dr. Ayesheh Enayati
Street address
Shastkola Road
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
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enayati_phyto@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Golestan University of Medical Sciences
Proportion provided by this source
50
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
South Khorasan Academic center for education, culture and research
Full name of responsible person
Dr. Mahdi Ebrahimi
Street address
Birjand - Pasdaran St. - Quds St
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Province
South Khorasan
Postal code
466
Phone
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Email
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Web page address
http://jdkhj.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
South Khorasan Academic center for education, culture and research
Proportion provided by this source
33
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

3

Sponsor
Name of organization / entity
Food and Bio-Nanotech International Research Center (Fabiano)
Full name of responsible person
Elham Assadpour
Street address
Gorgan University of Agricultural Science and Natural Resources
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49138-15739
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Email
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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
Food and Bio-Nanotech International Research Center (Fabiano)
Proportion provided by this source
33
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Ayesheh Enayati
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Assistant Professor
Latest degree
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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
No - There is not 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