

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

Ayeshah 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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enayati_phyto@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Dr. Ayesheh Enayati

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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

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

+98 17 3225 1701

Email

smjafari@gau.ac.ir

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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Birjand

Province

South Khorasan

Postal code

466

Phone

+98 56 1222 3006

Email

Sec.khj@acecr.ac.ir

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

City

gorgan

Province

Golestan

Postal code

49138-15739

Phone**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

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Ayesheh Enayati

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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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