Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The effect of Ziziphus Jujuba syrup on the lipid profile and oxidative stress in hyperlipidemic- hypertensive patients

Protocol summary

Study aim
Determining the effect of jujube syrup on lipid profile and oxidative stress in hyperlipidemic patients with high blood pressure

Design
Clinical trial with a control group, with parallel groups, without blinding, randomized, phase 3 on 36 patients. PASS software will be used for randomization

Settings and conduct
This study will be with the participation of patients with primary or uncontrolled hypertension & Hyperlipidemic refer to Bahlul clinic. after Examination of people the samples will be randomly assigned to two groups of control and intervention by the method of 4 permutation blocks. For subsequent measurements, within two month (4 week , 8 week), the patient's blood draw, and test results will be recorded at the office of the same specialist doctor. In addition to the routine treatment, the intervention group was given jujube syrup and they were asked to consume 5 cc twice a day. It should be noted that the participants in the intervention group will not be deprived of changing their routine treatment and adding a new drug due to blood pressure control in the present plan. In order to ensure regular consumption and prevent forgetting to take the medicine, a table including the number of study days also be given to them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study, having systolic blood pressure above 14 and diastolic above 8, confirmed and controlled by a doctor for at least one year, high level of at least one lipid profile parameter. Conditions of non-entry: having other cardiovascular diseases, pregnancy, breastfeeding

Intervention groups
Control group: usual treatment protocol Intervention group: routine treatment+ jujube syrup(they were asked to consume 5 cc twice a day(

Main outcome variables
Cholesterol; Triglyceride; Low-density lipoprotein; High-density lipoprotein; Malondialdehyde; Glutathione

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240622062206N2**
Registration date: **2025-06-01, 1404/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-01, 1404/03/11**
Update count: **0**

Registration date
2025-06-01, 1404/03/11

Registrant information

Name
Nasim Khajavian

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
2025-04-04, 1404/01/15

Expected recruitment end date
2025-06-05, 1404/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Ziziphus Jujuba syrup on the lipid profile and oxidative stress in hyperlipidemic- hypertensive patients

Public title
Ziziphus Jujuba extract syrup in hypertension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Having systolic blood pressure above 14 and diastolic above 8, confirmed and controlled by a doctor for at least one year Elevation of at least one lipid profile parameter
Exclusion criteria:
Having other cardiovascular diseases Pregnancy Breastfeeding
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups. Samples will be divided into two experimental and control groups based on permutation blocks (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly and the arrangement of receiving intervention will be determined accordingly
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Medicine of Gonabad University of Medical Sciences
Street address
Dr. Mahdizadeh Blvd., Gonabad University of Medical Sciences
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2025-02-04, 1403/11/16
Ethics committee reference number
IR.GMU.REC.1403.132

Health conditions studied

1

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

2

Description of health condition studied
Hyperlipidemia
ICD-10 code
E78.5
ICD-10 code description
Hyperlipidemia, unspecified

Primary outcomes

1

Description
Cholesterol
Timepoint
At the beginning of the study (before the start of the intervention) and 4 and 8 weeks after starting jujube syrup consumption
Method of measurement
Blood test

Secondary outcomes

1

Description
Triglycerides
Timepoint
At the beginning of the study (before the start of the intervention) and 4 and 8 weeks after starting jujube syrup consumption
Method of measurement
Blood test

2

Description

Low-density lipoprotein

Timepoint

At the beginning of the study (before the start of the intervention) and 4 and 8 weeks after starting jujube syrup consumption

Method of measurement

Blood test

3

Description

High-density lipoprotein

Timepoint

At the beginning of the study (before the start of the intervention) and 4 and 8 weeks after starting jujube syrup consumption

Method of measurement

Blood test

4

Description

Malondialdehyde

Timepoint

At the beginning of the study (before the start of the intervention) and 4 and 8 weeks after starting jujube syrup consumption

Method of measurement

Blood test

5

Description

Glutathione

Timepoint

At the beginning of the study (before the start of the intervention) and 4 and 8 weeks after starting jujube syrup consumption

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: The jujube fruit with the scientific name Ziziphus jujuba is identified after purchase from the medicinal plant centers of Birjand city and 100 grams of dried seedless jujube are mixed and mixed in powder form with 400 cc of 50% ethanol for 72 hours (water-alcoholic extract by soaking method), then extraction is carried out with different filters and removal of pulp is carried out, and finally the extract is concentrated under the temperature of the incubator. In the next stage, considering the optimal dose of jujube extract in studies investigating animal blood pressure (200 mg/kg of animal weight), the human dose is calculated as one-seventh and is calculated as 30 mg per kilogram of human weight. Therefore, for a 60 kg human, the total dose is 1800 mg of extract. The syrup will be prepared with a concentration such that every 5 cc contains 900 mg of extract, and each person will use 10 cc of syrup per day for two months. The amount of extract required, based on a dose of 900 mg in 5 cc, will be 18% concentration of jujube extract in syrup.

Category

Treatment - Drugs

2

Description

Control group: Control group: They use their common hypertension drugs to control their blood pressure for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohlool Hospital

Full name of responsible person

Reza mohebbati

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Sadi Ave., Parastar Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Reza Mohebbati
Position
Assistant Professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available