Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Trachyspermum ammi(ajwain) extract on blood pressure of patients at risk for hypertension referring to Afshar cardiac Clinic in Yazd

Protocol summary

Study aim
Evaluation of the effect of Ajwain extract as an add-on therapy on blood pressure control, lipid profile, and fasting blood sugar in patients with hypertension

Design
A controlled, parallel-group, double-blind, randomized clinical trial on 80 patients. Individual block randomization and computer statistical software were used for randomization.

Settings and conduct
Eligible patients will be individually allocated to the two groups using individual block randomization and statistical software. To maintain blinding, the capsules for both groups are completely identical in appearance and labeled with anonymous codes, and the participants, caregivers, researchers, assessors are kept blind to the patients' group allocation. The study location is the Cardiology Clinic of Afshar Hospital in Yazd.

Participants/Inclusion and exclusion criteria
Participants: Patients with hypertension referred to the cardiology clinic of Afshar Hospital in Yazd. Inclusion Criteria: Diagnosis of Hypertension; Use of Antihypertensive Medication; Informed Consent and Protocol Adherence Exclusion Criteria: Pregnancy or Lactation; Specific Diseases; Acute Infectious or Inflammatory Diseases; History of Allergy to Ajwain; History of Severe Drug Side Effects; Consumption of Alcohol; Use of Calcium Channel Blockers

Intervention groups
In this study, two parallel intervention groups will participate. The active intervention group will receive a capsule containing 250 mg of standardized Ajwain Extract orally, twice a day, for 8 consecutive weeks. In contrast, the control group will also consume a placebo capsule containing edible starch powder, with the same dose and in the same manner. The placebo capsules have been prepared to be visually completely similar to the Ajwain extract to fully maintain the blinding principle.

Main outcome variables
Change in mean systolic blood pressure; change in mean diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251207068231N1**
Registration date: **2025-12-14, 1404/09/23**
Registration timing: **prospective**

Last update: **2025-12-14, 1404/09/23**
Update count: **0**

Registration date
2025-12-14, 1404/09/23

Registrant information

Name
Mohammadhasan Fakhari Zavareh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3841 2940

Email address
mhfz1378@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01

Expected recruitment end date
2026-06-20, 1405/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Trachyspermum ammi(ajwain) extract on blood pressure of patients at risk for hypertension referring to Afshar cardiac Clinic in Yazd

Public title
The effect of ajwain (Trachyspermum ammi) extract on blood pressure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Hypertension Antihypertensive Medication Use Informed Consent and Protocol Adherence People between the ages of 20 and 60

Exclusion criteria:
Pregnant or lactating women Patients with severe hepatic or renal impairment Individuals with specific cardiovascular diseases, such as severe aortic stenosis, acute heart failure, or unstable cardiovascular diseases (e.g., unstable angina), where the condition may be exacerbated by changes in blood pressure. The presence of acute infectious or inflammatory diseases at the time of study initiation History of any allergic reaction to Ajwain or other plants of the Apiaceae family (such as celery, parsley) History of any intolerable and severe side effects, such as severe drop in blood pressure (hypotension) or allergic reaction to antihypertensive drugs Consumption of alcohol or other drugs that may affect drug metabolism and general health status. A person taking calcium channel blockers (such as Amlodipine, Nifedipine, and Diltiazem) will not be enrolled in the study because the potential interaction of Ajwain with these drugs may cause a synergistic effect and lead to hypotension.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization will be utilized to allocate eligible participants to the intervention (Ajwain extract) and control (placebo) groups. The unit of randomization is individual, with each participant being independently randomized. The randomization tool will be a statistical software package. The random allocation sequence will be generated by a specialized statistician independent of the research team and applied as anonymous codes to the treatment capsules. For allocation concealment, the study will be conducted as a double-blind trial. Both the Ajwain extract and placebo capsules are prepared to be completely identical in appearance and are labeled only with these anonymous codes. The master list, which links the codes to the actual treatment allocation (Ajwain extract or placebo), will remain sealed with the independent statistician until the completion of data collection and final statistical analysis.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, four main groups of individuals are kept blinded to prevent bias: Participants: They are unaware of the actual nature of the substance received (Ajwain extract or placebo) due to receiving identical and coded capsules. Clinical Care Providers: Personnel responsible for patient care and follow-up remain unaware of each patient's treatment group due to allocation based on code and the identical appearance of the medications. Researchers (Principal and Executive): The research team, during the execution phase and data collection, are unaware of the patients' group allocation due to lack of access to the code-breaking list (master list). Outcome Assessors and Data Collectors: Individuals who record the data and evaluate the study outcomes are kept blinded to the treatment group to ensure impartial recording.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Baqiyatallah university of medical sciences

Street address
Sheikh Bahai Street, Vanak Square, Mulla Sadra Square, Baqiyatallah University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2025-11-17, 1404/08/26

Ethics committee reference number
IR.BMSU.REC.1404.142

Health conditions studied

1

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

Primary outcomes

1

Description
systolic blood pressure
Timepoint
At the start of the study, week four, week eight
Method of measurement
Blood Pressure Monitors

2

Description
Diastolic blood pressure
Timepoint
At the start of the study, week four, week eight
Method of measurement
Blood Pressure Monitors

Secondary outcomes

1

Description
HDL Cholesterol
Timepoint
At the start of the study, week eight
Method of measurement
Measuring the amount of HDL in patients' blood samples

2

Description
LDL Cholesterol
Timepoint
At the start of the study, week eight
Method of measurement
Measuring the amount of LDL in patients' blood samples

3

Description
Triglycerides
Timepoint
At the start of the study, week eight
Method of measurement
Measuring the amount of triglycerides in patients' blood samples

4

Description
ALT enzyme level
Timepoint
At the start of the study, week eight
Method of measurement
Measuring the amount of ALT enzyme measured in patients' blood samples

5

Description
AST enzyme level
Timepoint
At the start of the study, week eight
Method of measurement
Measuring the amount of AST enzyme measured in patients' blood samples

6

Description
FBS Level
Timepoint
At the start of the study, week eight
Method of measurement
Measuring blood sugar after fasting for at least 8 hours

Intervention groups

1

Description
Standardized extract of the plant Ajwain (Trachyspermum ammi).Form and Dosage: This group will receive 250 mg oral capsules containing the Ajwain extract.Standardization and Composition: The extract is standardized based on its main active constituent, Thymol. The concentration of Thymol in the extract should be between 20% and 40%.Daily Dosage: 500 mg of the extract per day (two 250 mg capsules).Frequency: One capsule every 12 hours (twice daily).Duration of Consumption: 8 weeks.Method of Consumption: The capsules are consumed orally with water.
Category
Treatment - Drugs

2

Description
Control group: Substance Used: Placebo capsule containing edible starch powder as a neutral filler. This substance has no pharmacological or therapeutic effect. Dosage: Each participant will receive the placebo equivalent to the volume of the intervention group's capsules (250 milligrams).Frequency and Method of Administration: The administration will be oral in the form of capsules, taken twice a day. This regimen is exactly the same as the intervention group. Duration of Consumption: The duration of placebo consumption will be completely identical to the intervention group, lasting for 8 consecutive weeks.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Sadegh Afshar Hospital
Full name of responsible person
Seyed Ali Sadr Bafghi
Street address
Mohammad Sadegh Afshar Hospital, Jomhuri Islami Blvd
City
Yazd
Province
Yazd
Postal code
۸۹۱۷۹۴۴۵۴۱
Phone
+98 35 3160 2152
Email
afshar.rdc@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mahdi Bagheri
Street address
mollasadra st, vanak sq., sheykh bahayi st.
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8755 4574
Email
mbagheri.pharm@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammadhasan Fakhari Zavareh
Position
Researcher
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No. 4, Ostad Karami Alley, Ma'refat Street, Andisheh Town, Mehravran, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8915897331
Phone
+98 35 3841 2940
Fax
Email
mhfz1378@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mahdi Bagheri
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, South Sheikh Bahaei Street, Molla Sadra Street, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8755 4574
Email
mbagheri.pharm@gmail.com

Person responsible for updating data

mhfz1378@gmail.com

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Mohammadhasan Fakhari Zavareh

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
No. 4, Ostad Karami Alley, Ma'refat Street, Andisheh Town, Mehravran, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8915897331

Phone
+98 35 3841 2940

Fax

Email

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