Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating Asrol Capsule as an Add-on to Standard Treatment for Primary Hypertension: A Randomized, Double-blind, Placebo-controlled Trial

Protocol summary

Study aim
Mean changes in systolic and diastolic blood pressure, pulse pressure, and treatment response by sex, and concomitant antihypertensive medication types and numbers.

Design
Phase 2, randomized, double-blind, parallel-group, placebo-controlled clinical trial on 92 patients. Patient allocation to the intervention and control groups was performed using the minimization method to balance age, sex, and temperament

Settings and conduct
This randomized, double-blind, placebo-controlled trial at Iran University of Medical Sciences involves patients with primary hypertension (stages I-II). For 6 weeks, patients receive standard care plus Asrol or placebo (twice daily). Allocation uses minimization, keeping patients, evaluators, and researchers blinded. Blood pressure is measured at baseline and weeks 2, 4, and 6; lab tests are evaluated at baseline and study end.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients aged 18 to 80 years with stage one or two primary hypertension Exclusion Criteria: Very high blood pressure; cardiovascular or cerebrovascular diseases; allergy; use of neurological medications, anticoagulants, antiplatelet drugs; hypothyroidism medications; liver or kidney disease; pregnancy; breastfeeding; history of peptic ulcer; gynecomastia; sexual dysfunction; nasal issues

Intervention groups
Control group: Standard treatment+ placebo
Intervention group: Standard treatment + Asrol

Main outcome variables
Mean systolic and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130207012391N3**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **prospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

Registration date
2026-08-10, 1405/05/19

Registrant information
Name
Roshanak Ghods
Name of organization / entity
Tehran University of Medical Sciences - Faculty of Traditional Medicine
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-11, 1405/06/20

Expected recruitment end date
2027-06-21, 1406/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating Asrol Capsule as an Add-on to Standard Treatment for Primary Hypertension: A Randomized,

Double-blind, Placebo-controlled Trial

Public title
Investigating the Effect of Asrol Capsule on Hypertension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 80 years Diagnosis of primary hypertension, stage I or II, based on the AHA 2025 guideline Patients determined by a cardiologist to be candidates for initiation of pharmacologic treatment
Exclusion criteria:
Baseline blood pressure greater than 180/110 mmHg Patients with angina syndromes, unstable angina, myocardial infarction, heart failure, stroke, or other cardiovascular diseases History of any allergy to medicinal plants, including borage, lemon balm, lavender, chamomile, rose, orange blossom, lemon verbena, coriander seed, valerian, bilberry, hibiscus, black seed, or acerola root Use of hypnotic or sedative medications Patients with depression or those currently taking antidepressant medicationsUse of digitalis glycosides Use of neuroleptic drugs, barbiturates, or levodopa Use of sympathomimetic drugs, including cough and cold medications or appetite suppressants Use of anticoagulant or antiplatelet medications Use of digitalis glycosides Alcohol consumption Hypothyroidism Liver disorders or renal failure Pregnancy or breastfeeding History of gastrointestinal ulcers Bradycardia Patients complaining of impotence or decreased libido Gynecomasti Patients with a history of nasal polyps, severe nasal congestion, or recurrent epistaxis
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random sampling will be used to recruit eligible participants with primary hypertension. After screening based on the predefined inclusion and exclusion criteria, a unique identification number will be assigned to each eligible individual, and the required number of participants will be selected using a random numbers table. Conventional randomization methods are not effective in randomized clinical trials of Persian medicine because they do not take individuals' temperament characteristics into account. During the randomization process, the treatment groups may differ significantly in some prognostic and temperament-related factors, particularly when the sample size is relatively small (less than 200). If these factors have important effects on the study's primary or secondary outcomes, any significant differences in the levels of these factors will affect the trial results. Various methods are used to overcome the problem of unmatched experimental groups, including minimization and stratification, with minimization providing more acceptable
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind trial. To maintain blinding, the Asrol capsules and their placebo will be identical in terms of shape, size, color, packaging, and labeling. In addition, the placebo for the standard antihypertensive medication will be similar to the active product in appearance and administration schedule. Accordingly, all participants in both groups will receive the standard medication and the study capsules in similar packaging, and participants, investigators, and outcome assessors will remain unaware of group allocation. The allocation code will be kept by the statistician until the end of the study, and the participants, investigators, and outcome assessors will remain unaware of group allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Secretariat of the Ethics Committee, Vice-Chancellor for Research and Technology, 5th Floor, Central Headquarters, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway, Tehran, Iran
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۱۴۴۹۶۱۴۵۳۵
Approval date
2026-07-13, 1405/04/22
Ethics committee reference number
IR.IUMS.REC.1405.239

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
110
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Mean systolic blood pressure of the patient, measured in millimeters of mercury (mmHg) after at least 5 minutes of rest.
Timepoint
At baseline and at weeks 2, 4, and 6 after the start of the intervention
Method of measurement
Standard digital upper-arm sphygmomanometer (Omron brand)

2

Description
Mean diastolic blood pressure of the patient, measured in millimeters of mercury (mmHg) after at least 5 minutes of rest.
Timepoint
At baseline and at weeks 2, 4, and 6 after the start of the intervention
Method of measurement
Standard digital upper-arm sphygmomanometer (Omron brand)

Secondary outcomes

1

Description
Mean pulse pressure of the patient (calculated as the difference between systolic and diastolic blood pressure).
Timepoint
At baseline, and at weeks 2, 4, and 6 after the start of the intervention.
Method of measurement
Calculated formula (Pulse Pressure=SBP−DBP) based on measurements from a standard digital sphygmomanometer.

2

Description
Blood and Urine Sodium (Na) level
Timepoint
At baseline and at the end of week 6
Method of measurement
Standard laboratory blood and urine test

3

Description
Blood Potassium (K) level
Timepoint
At baseline and at the end of week 6
Method of measurement
Standard laboratory blood test

4

Description
Blood Urea Nitrogen (BUN) level
Timepoint
At baseline and at the end of week 6
Method of measurement
Standard laboratory blood test

5

Description
Blood Creatinine (Cr) level
Timepoint
At baseline and at the end of week 6
Method of measurement
Standard laboratory blood test

6

Description
Liver enzyme SGOT (Serum Glutamic-Oxaloacetic Transaminase or AST) level
Timepoint
At baseline and at the end of week 6
Method of measurement
Standard laboratory blood test

7

Description
Liver enzyme SGPT (Serum Glutamic-Pyruvic Transaminase or ALT) level
Timepoint
At baseline and at the end of week 6
Method of measurement
Standard laboratory blood test

Intervention groups

1

Description
Control group: Patients in this group receive standard antihypertensive medications along with a 500 mg placebo capsule (containing wheat starch). The placebo capsules are identical to the Asrol capsules in appearance, size, color, taste, and packaging. The medication is administered orally, twice a day (one capsule after breakfast and one after dinner), for a duration of 6 weeks.
Category
Placebo

2

Description
Intervention group: Patients in this group receive standard antihypertensive medications along with a 500 mg herbal “Asrol” capsule (manufactured by Talaye Sabze Tooba Company). The capsule contains a mixture of 13 medicinal herbs: Borage, Lemon balm, Orange blossom, Lavender, Chamomile, Rose, Lemon verbena, and Coriander seed (30.1 mg each); Valerian, Cranberry, and Sour tea (60.2 mg each); Nigella sativa and Asrol root (39.13 mg each). The medication is administered orally, twice a day (one capsule after breakfast and one after dinner), for a duration of 6 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran University of Medcial Sciences

Full name of responsible person
Fereshteh Fathi

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Persian Medicine Clinic, Persian Medicine School of Iran University of Medical Sciences, Behesht Intersection, Vahdat-e-Eslami St.

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Roshanak Ghods

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Other areas of specialty/work
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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
No - There is not 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
Yes - There is 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
Title and more details about the data/document
Publication of data after analysis in the form of an original research article
When the data will become available and for how long
After article publication
To whom data/document is available
everyone
Under which criteria data/document could be used
There is no restriction if the article is cited accurately
From where data/document is obtainable
Journal site
What processes are involved for a request to access data/document
If the journal does not charge for access, the content will be available by downloading the paper.
Comments