Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the effect of Althaea officinalis extract oral solution on blood pressure levels in patients with high blood pressure (HTN): A randomized double blind clinical trial

Protocol summary

Study aim

To determine the effect of the oral solution of hibiscus extract on systolic blood pressure in individuals with hypertension after 2 weeks of consumption and to compare it with a placebo.

Design

A controlled clinical trial with parallel groups, double-blind, randomized, Phase 2 study on 70 patients. Consultation with statistical experts was sought for randomization

Settings and conduct

The study is a double-blind clinical trial. Both the therapist and the patient are unaware of the medication given. Patients with hypertension who are being treated with oral antihypertensive medications and have poor control will be selected for outpatient visits to the Iranian Traditional Medicine Health Center of Jundi Shapur in Ahvaz. In the treatment group, in addition to antihypertensive medications, an oral solution of marshmallow extract prepared by Zarband Pharmaceutical Company will be administered twice daily at a dosage of 10 milliliters for two weeks. In the placebo group, in addition to their previous medications, a placebo will be given twice daily at twelve-hour intervals for two weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age between 25 and 70 years Blood pressure of 90/140 mmHg or higher Patients should only be using oral antihypertensive medications. Exclusion Criteria Pregnancy Breastfeeding Significant renal failure Liver failure

Intervention groups

The treatment group will receive, in addition to antihypertensive medications, an oral solution of marshmallow extract prepared by Zarband Pharmaceutical Company, administered twice daily at a dosage of 10 milliliters for two weeks. The placebo group will receive a placebo in addition to their previous medications, also administered twice daily at twelve-hour intervals. These medications will be given to the patients for a duration of two weeks.

Main outcome variables

Control and Reduction of Blood Pressure

General information

Reason for update

Change of work location due to closure of traditional medicine clinic

Acronym

IRCT registration information

IRCT registration number: **IRCT20250603066044N1**
Registration date: **2025-07-13, 1404/04/22**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-22, 1404/06/31**
Update count: **1**

Registration date

2025-07-13, 1404/04/22

Registrant information

Name

Neda Sitani karampour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3338 0031

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-21, 1404/03/31

Expected recruitment end date

2025-07-20, 1404/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Althaea officinalis extract oral solution on blood pressure levels in patients with high blood pressure (HTN): A randomized double blind clinical trial

Public title

The effect of hibiscus flower extract on blood pressure.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Blood pressure of 90/140 mmHg or higher Patients should only use oral antihypertensive medications

Exclusion criteria:

Pregnancy Lactation Severe renal failure Liver failure

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The permutation block randomization method is used. Blocking is usually used to balance the number of samples allocated to each of the study groups. This feature helps researchers to ensure that the number of samples allocated to each of the study groups is equal in cases where interim analyses are needed during the sampling process. In this two-group clinical trial, the block size is 4. The allocation ratio between the two groups is 1:1. The randomization tool is the blockrand package of R software. For concealment, we use random allocation concealment. This method is used to perform random sequence on participants in such a way that the assigned group is not known before the individual is assigned. Using sealed opaque envelopes with a random sequence, in which each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the envelopes are sealed and placed in a box in order. When participant registration begins, based on the order of entry into the study, one of the envelopes is opened in order and the assigned group of that participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

To control the entry criteria for the study, the initial visit will be conducted by a physician. Coded medications will be prepared and delivered to the study assistant, who will not be informed about the types of medications. The codes will be sent separately in sealed envelopes so that neither the researcher nor the patient will be aware of the contents of the medication container until the end of the study. The medications will be administered to the patients by the study assistant using a random block method. Patients will be divided into two groups (35 individuals in each group) using a randomization list prepared by a statistical consultant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestat Blvd,Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6155833651

Approval date

2025-04-18, 1404/01/29

Ethics committee reference number

IR.AJUMS.REC .1404.051

Health conditions studied

1

Description of health condition studied

Essential (primary) hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description
Measuring Blood Pressure
Timepoint
It will be measured 5 times over the course of 2 weeks.
Method of measurement
Using a blood pressure monitor

Secondary outcomes

1

Description
FBS TG LDL HDL
Timepoint
Beginning and end of the test
Method of measurement
Blood sampling

Intervention groups

1

Description
Intervention group: Intervention group: In addition to antihypertensive medications, an oral solution of hibiscus extract prepared by Zarband Pharmaceutical Company will be administered twice daily for 2 weeks, with each dose being 10 milliliters
Category
Treatment - Drugs

2

Description
Control group: Placebo: In addition to antihypertensive drugs, a carrier solution containing an oral extract of hibiscus flower without active ingredients, prepared at the Faculty of Pharmacy in Ahvaz, will be administered for 2 weeks, twice a day, with each dose being 10 milliliters
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Seyed Isai Marazi's office, Mahshahr city, Sarbandar district
Full name of responsible person
Fatemeh Amini
Street address
Golestan Blvd AhvazJundishapueUniversity Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abdolah Rafiei
Street address
Golestan Blvd , Ahvaz Uuniversity of Medical Sciences
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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
Ahvaz jundishapur 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
Ahvaz University of Medical Sciences
Full name of responsible person
Neda Sistani karampour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work

Medical Pharmacy

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Position
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Person responsible for updating data

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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