

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of adding Gaznab herbal product to standard treatment in patients with primary hypertension compared to placebo

Protocol summary

Study aim

The aim of this study was to evaluate the effect of Gaznab herbal product on lowering blood pressure in patients with grade 1 hypertension (systole 159-140 and diastole 99-90 mm Hg).

Design

This study is a randomized clinical trial, including intervention and control groups with parallel, three-way blind groups. Patients are randomly divided into intervention and control groups using www.sealedenvelop.com. The method of hiding the allocation is by the method of closed envelope, opaque and sealed. The sample size is 18 people in each group.

Settings and conduct

The project site is the heart clinics of Imam Reza Hospital in Mashhad. Patients randomly receive 8 weeks of Gaznab syrup or placebo syrup. In this study, three blind patients and outcome evaluators and data analyzers were assigned Unaware of groups. The 36-item Quality of Life Questionnaire and the DASS21 Stress, Anxiety and Depression Inventory are completed at the beginning and end of the study for patients.

Participants/Inclusion and exclusion criteria

Men and women aged 30-65 years Hypertension grade1 with pressure equal to or greater than 140.90 mmHg to 159.99 mmHg BMI greater than or equal to 27 Major conditions of non-inclusion: presence of blood pressure greater than or equal to 180/110 mm Hg History of hypo or hyperthyroidism Warfarin consumption Pregnancy or lactation The presence of any medical or surgical disorder that could interfere with the study

Intervention groups

The intervention group was given 10 ml of herbal syrup twice a day and continued with the previous drugs, and the control group was given 10 ml of placebo syrup twice a day with the continuation of the previous drugs for 8 weeks.

Main outcome variables

Change in blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210622051660N1**

Registration date: **2021-07-15, 1400/04/24**

Registration timing: **prospective**

Last update: **2021-07-15, 1400/04/24**

Update count: **0**

Registration date

2021-07-15, 1400/04/24

Registrant information

Name

batool jalalkamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5008

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-17, 1400/04/26

Expected recruitment end date

2022-07-17, 1401/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding Gaznab herbal product to standard treatment in patients with primary hypertension compared to placebo		Assignment Parallel
		Other design features
Public title	Evaluation of the effect of Gaznab herbal product on the control of primary hypertension	Secondary Ids empty
Purpose	Treatment	Ethics committees
Inclusion/Exclusion criteria	Inclusion criteria: Men and women aged 30-65 years Hypertension grade1 with pressure equal to or greater than 140.90 mmHg to 159.99 mmHg Are treated with a blood pressure medication (one to three drugs based on the protocol). BMI greater than or equal to 27 At least one month has passed since starting the medication The person should not be at high risk (diabetes mellitus and end organ damage , etc.) Exclusion criteria: History of hypo or hyperthyroidism Types of cardiac dysrhythmias (such as second and third degree block) Allergy to medicinal plants History of potassium greater than 5.1 or less than 3.5 m Eq / L at the first visit Warfarin consumption Pregnancy or lactation History of hypermenorrhea in females Presence of blood pressure greater than or equal to 180/110 mm Hg The presence of any medical or surgical disorder that could interfere with the study.	1 Ethics committee Name of ethics committee Ethics committee of mashhad University of Medical Sciences Street address Mashhad Univercity Of Medical Sciences, University Street City Mashhad Province Razavi Khorasan Postal code 13944-91388 Approval date 2021-06-19, 1400/03/29 Ethics committee reference number IR.MUMS.REC.1400.059
Age	From 30 years old to 65 years old	Health conditions studied
Gender	Both	1 Description of health condition studied Hypertension ICD-10 code I10 ICD-10 code description Essential (primary) hypertension
Phase	3	Primary outcomes
Groups that have been masked	- Participant - Outcome assessor - Data analyser	1 Description Blood pressure Timepoint In baseline and after 4 week and after 8 week Method of measurement Sphygmomanometer
Sample size	Target sample size: 36	2 Description FBS, BUN, Cr, TG, Cholesterol, SGOT, SGPT, CBC Timepoint Beginning and end of the study (after 8 weeks) Method of measurement Biochemical and Hematological blood check
Randomization (investigator's opinion)	Randomized	
Randomization description	Patients are divided into control and intervention groups using random blocking method by www.sealedenvelop.com. How to hide the allocation with the envelope method is sealed opaque and sealed.	
Blinding (investigator's opinion)	Triple blinded	
Blinding description	In this study, patients are unaware that they are assigned to the control or intervention group. intervention group will be given Gaznab herbal syrup and continuation of previous drugs and the control group will be given placebo syrup and continuation of previous drugs(in the same package and color). The outcome assessor as well as the data analyst are unaware of which group the patient belongs to.	
Placebo	Used	

Secondary outcomes

jalalkb1@mums.ac.ir

1

Description

Quality of life score

Timepoint

pretest, post-test (at the end of 8 weeks)

Method of measurement

The World Health Organization Quality of Life Questionnaire

2

Description

Stress, Anxiety and Depression score

Timepoint

pretest, post-test (at the end of 8 weeks)

Method of measurement

DASS21 Questionnaire

Intervention groups

1

Description

Intervention group: Gaznab syrup containing aqueous extract of jujube with a concentration of 15% w / v and nettle with a concentration of 10% w / v 2 times a day and each time 10 cc for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo syrup of the same shape and color with the same packaging and 2 times a day and each time 10 cc for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Batool Jalalkamali

Street address

Imam Reza Hospital, Imam Reza Square, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Batool Jalalkamali

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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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