Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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

Public title
Evaluation of the effect of Gaznab herbal product on the control of primary hypertension
Purpose
Treatment
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.
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
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
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

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

Health conditions studied

1

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

Primary outcomes

1

Description
Blood pressure
Timepoint
In baseline and after 4 week and after 8 week
Method of measurement
Sphygmomanometer

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

Secondary outcomes

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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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