

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

A clinical trial comparing the effects of placebo and the Iranian traditional medicinal product of mao'ljabn or cheese-water on primary hypertension

Protocol summary

Study aim

To determine the impact of mao'ljabn or cheese-water on primary hypertension

Design

This clinical trial will be performed on patients aged 18 to 80 years with hypertension in stage 1. The patients include those who refer to Birjand Cardiovascular Clinic and are being treated with hypotensive drugs but whose blood pressure is not controlled yet. The patients will be randomly assigned into intervention and control groups via simple randomization.

Settings and conduct

Patients are randomly assigned into cheese water and placebo groups via simple randomization method and in blocs of 4. The intervention group receives 50 grams of cheese-water powder dissolved in bristled water twice daily before meals in the morning and evening for 6 weeks. The control group receives 50 grams of maltodextrin powder diluted in bristled water twice daily before meals in the morning and evening for 6 weeks. Patients are visited by the researcher every two weeks and by a cardiologist once a month.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: Men and women aged 18 to 80 years; Being in the first stage of hypertension (i.e., systolic blood pressure greater than or equal to 140, and diastolic blood pressure greater than or equal to 90 mmHg based on the new definition of the Joint National Committee-8; Being treated with blood pressure medication (one to a maximum of three drugs based on the protocol), but the patient's blood pressure is uncontrolled and still in stage 1 hypertension; minimum of one month passed from the onset of drug consumption; body mass index below 30. Main exclusion criteria: Stage 2 or above according to hypertension classification of the Joint National Committee-VIII; blood pressure greater than or equal to 110/180 mmHg; history of secondary hypertension (e.g., hyperaldosteronism, pheochromocytoma, renal artery stenosis, Cushing's

syndrome); endocrine disruption symptoms such as renal failure, congestive heart failure, myocardial infarction, or cerebrovascular accidents from the 6 months prior to the study onset; the presence of any type of cardiac arrhythmia (such as second- or third-degree blocks); and symptomatic heart valve disease (except for mitral valve prolapse)

Intervention groups

Intervention Group (cheese-water): 50 grams of cheese-water powder dissolved in bristled water consumed twice daily before meals in the morning and evening for 6 weeks. Control Group (maltodextrin): 50 grams of maltodextrin powder diluted in bristled water consumed twice daily before meals in the morning and evening for 6 weeks

Main outcome variables

Change in systolic and diastolic blood pressure; Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N34**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

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Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effects of placebo and the Iranian traditional medicinal product of mao'ljabn or cheese-water on primary hypertension

Public title

Impact of mao'ljabn or cheese-water on primary hypertension

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being in stage 1 hypertension (i.e., systolic blood pressure greater than or equal to 140, and diastolic blood pressure greater than or equal to 90 mmHg based on the new definition of the Joint National Committee-8
Being treated with blood pressure medication (one to a maximum of three drugs based on the protocol), but the patient's blood pressure is uncontrolled and still in stage 1 hypertension
A minimum of one month passed from the onset of drug consumption
Body mass index below 30
Age between 18 and 80 years

Exclusion criteria:

Stage 2 or above according to hypertension classification of the Joint National Committee-VIII
Blood pressure greater than or equal to 110/180 mmHg
History of secondary hypertension (e.g., hyperaldosteronism, pheochromocytoma, renal artery stenosis, Cushing's syndrome)
Endocrine disruption symptoms such as renal failure, congestive heart failure, myocardial infarction, or cerebrovascular accidents from the 6 months prior to the study onset
The presence of any type of cardiac arrhythmia (such as second- or third-degree blocks)
Symptomatic heart valve disease (except for mitral valve prolapse)
Type 1 and type 2 diabetic patients
Clinically significant renal and hepatic dysfunction, i.e., creatinine greater than 1.5 times the maximum normal and alanine aminotransferase more than 3 times the normal maximum
Number of platelets less than $\cdot 100,000$ or partial thromboplastin time more than 1.5
Pregnancy or breastfeeding intentions
Known or potential allergy to the tested product
Participation in any other clinical trials at the same time or within the last 30 days
History of

malignancy treated or untreated in the last 5 years
Chronic oral or intravenous treatment with corticosteroids
Serum potassium greater than 5.2 or less than 3.5 milliequivalents in the first visit
Consuming contraceptive pills or psychiatric drugs
History of drug abuse, alcohol abuse, etc.
Any disruption (medical or surgical) that can interfere with the study according to the investigator or another serious illness
The patient's inappropriate cooperation in the project or compromising the patient's safety or the incidence of any potential adverse effect by the drug
Childbirth during the project

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are allocated into study groups via simple random allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants are explained about the study objectives and procedures. Nonetheless, neither the patients nor the researchers know who has received the experimental drug.

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

Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

IR.IUMS.REC1396.9311661001

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**

systolic and diastolic blood pressure

Timepoint

Every two weeks from the study onset to two weeks after intervention

Method of measurement

Sphygmomanometer

2**Description**

Sleep quality

Timepoint

Every two weeks from the study onset to two weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes**1****Description**

Weight loss or gain

Timepoint

Every two weeks from the study onset to two weeks after intervention

Method of measurement

Digital scale

Intervention groups**1****Description**

Intervention Group (cheese-water): 50 grams of cheese-water powder dissolved in bristled water consumed twice daily before meals in the morning and evening for 6 weeks.

Category

Treatment - Drugs

2**Description**

Control Group (maltodextrin): 50 grams of maltodextrin powder diluted in bristled water consumed twice daily before meals in the morning and evening for 6 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hekmat-e Shargh Traditional Medicine Clinic

Full name of responsible person

Dr Maryam Navabzadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

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

70

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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified Individual Participant Data Set can be provided to other researchers.

When the data will become available and for how long

after the study report is published as a paper and for 2 years since the paper is published

To whom data/document is available

researchers who ask for it

Under which criteria data/document could be used

no certain criteria

From where data/document is obtainable

the personal email of researchers

What processes are involved for a request to access data/document

personal correspondence

Comments