# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**

**Name**

Mohammad Bagher Roozgar

**Name of organization / entity**

Birjand University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**
+98 56 3239 5680
**Email address**
mbroozgar@bums.ac.ir

**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 -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
**Street address**
Taleghani St.
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717853577
**Phone**
+98 56 3239 5000
**Email**
mnavab94@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Dr Seyed Kazem Malekouti
**Street address**
Hemmat Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 86701
**Email**
kmalakouti@ums.ac.ir
**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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Maryam Navabzadeh

**Position**

PhD Candidate of Iranian Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Ghaffari St.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Email**

mnavab94@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Maryam Navabzadeh

**Position**

PhD Candidate of Iranian Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Phone**

+98 56 3239 5000

**Email**

mnavab94@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Mohammad Bagher Roozgar

**Position**

PhD Candidate of Translation Studies

**Latest degree**

Master

**Other areas of specialty/work**

Translation

**Street address**

Ghaffari St.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5680

**Email**

hadirooz@gmail.com

## 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**