

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation of effect of dietary habit corrected by Iranian traditional medicine on blood pressure in patients with hypertension (HTN)

#### Protocol summary

##### Study aim

Determining the effect of dietary recommendations related to traditional Iranian medicine on blood pressure

##### Design

Clinical trials have an intervention group, with a parallel, single blind, randomized group, on 50 patients in each group. For randomization, Limited randomization method (Random allocation rule) was used.

##### Settings and conduct

Since the main action in controlling blood pressure in people who are in the pre-hypertensive stage is lifestyle modification, in this study, which is done in a single blind, we will try to examine the effect of modifying eating habits based on the principles of traditional Iranian medicine on the blood pressure of these people. At the outset Be checked Blood pressure. People will be monitored for one month to check their compliance with the instructions, as well as record their daily activity and diet in the delivered forms. On the 30th day, they will be invited again and their blood pressure will be measured. Nutritionist and evaluators will not be aware of the type of membership in the intervention and control group. This study is performed at the Cardiac Research Center of Afshar Hospital in Yazd.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Patients who are in the stage of prehypertension and have no evidence of secondary hypertension, Patients in the age range of 25 to 55 years  
Exclusion criteria Patients who enter the next stages of high blood pressure during the period, and those who suffer from cardiovascular disease and other diseases.

##### Intervention groups

In the intervention group, the correct method of eating will be taught according to the instructions of traditional Iranian medicine and also the training of blood pressure control diet. In the control group, only blood pressure control diet training will be given.

##### Main outcome variables

systolic blood pressure, diastolic blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200524047558N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

##### Registration date

2020-06-12, 1399/03/23

##### Registrant information

##### Name

hossein abolhosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 9824 5367

##### Email address

h.abolhosseini@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-11-20, 1399/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of dietary habit corrected by Iranian traditional medicine on blood pressure in patients with hypertension (HTN)

**Public title**

Evaluation dietary habit corrected by Iranian traditional medicine on blood pressure

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who are in the pre-hypertension stage and have no evidence of secondary hypertension. Patients in the age range of 25 to 55 years have a minimum diploma education

**Exclusion criteria:**

Patients with hypertension who enter the next stages of the disease. Those who have complications following dietary recommendation People with cardiovascular disease and other chronic diseases Those who have not complied with the relevant recommendations for more than one consecutive week or two Intermittent weeks

**Age**

From **25 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To randomize, a limited randomization model (Random allocation rule) will be performed, in which a ball of the same color and shape will be poured into a container. Will select and based on that the intervention and control group will be identified

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Invited patients who have been randomly assigned to two intervention and control groups will be trained on a blood pressure control diet separately after obtaining informed consent. Also, in the intervention group, Dietary recommendations training based on traditional Iranian medicine will be given. The Pamphlets and delivery forms in both groups have the same shape and there is no difference in their appearance. A nutritionist who is responsible for the nutrition counseling of both groups will not be aware of the type of membership in the intervention and control group and will equally follow the diet training. Evaluators of the primary and secondary consequences will also not be aware of the type of membership of the individuals studied.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of kerman University of Medical Sciences

**Street address**

Amir Kabir Crossroads, in front of the Faculty of Engineering, next to Shahid Mahdavi High School, Faculty of Traditional Iranian Medicine , Kerman

**City**

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**Province**

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**Postal code**

7618843883

**Approval date**

2020-02-24, 1398/12/05

**Ethics committee reference number**

IR.KMU.REC.1398.732

**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**

The amount of blood pressure systolic and diastolic

**Timepoint**

The first day of study and the 30th day of study

**Method of measurement**

Breuer digital blood pressure monitor

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

Weight

**Timepoint**

The first day of study and the 30th day of study

**Method of measurement**

Breuer digital scales

## 2

### **Description**

Waist circumference size

### **Timepoint**

The first day of study and the 30th day of study

### **Method of measurement**

Meter

## 3

### **Description**

neck circumference size

### **Timepoint**

The first day of study and the 30th day of study

### **Method of measurement**

Meter

## 4

### **Description**

body mass index

### **Timepoint**

The first day of study and the 30th day of study

### **Method of measurement**

calculation

## 5

### **Description**

body fat mass

### **Timepoint**

The first day of study and the 30th day of study

### **Method of measurement**

calculation

## 6

### **Description**

blood Triglyceride

### **Timepoint**

The first day of study and the 30th day of study

### **Method of measurement**

Autoanalyzer device

## 7

### **Description**

blood Cholesterol

### **Timepoint**

The first day of study and the 30th day of study

### **Method of measurement**

Autoanalyzer device

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this group, first, the level of awareness of dietary habit based on Iranian traditional medicine is measured. Then the necessary training is given to follow these instructions and also the diet to

control blood pressure is taught. During one month, the compliance with these instructions as well as the diet is controlled.

#### **Category**

Lifestyle

### 2

#### **Description**

Control group: In this group, only the necessary training to follow the blood pressure control diet is given, and during one month of study, the observance of these diets is controlled.

#### **Category**

Lifestyle

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Yazd Cardiovascular Research Center

##### **Full name of responsible person**

Dr. Seyed Mostafa Seyed Hosseini

##### **Street address**

Afshar Hospital Jomhouri Boulevard. Yazd, Iran

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##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Dr. Abbas Pardakhi

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at the beginning of Ibn Sina Street ,Somayeh Crossroads, Deputy of Research and Technology, Kerman medical university

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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**  
Kerman 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**  
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Kerman University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Satayesh  
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## Person responsible for updating data

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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**

After identifying the participants' details, the information about the main consequences will be shared

**When the data will become available and for how long**

one year after the end of the study

**To whom data/document is available**

Researchers working in academic and scientific

institutions

**Under which criteria data/document could be used**

For researchers, the use of the questionnaire and the consent form, as well as statistical information of the study, if the proposal is sent and the intellectual rights of the researcher are unrestricted

**From where data/document is obtainable**

Email msetayeshmail@gmail.com

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

If you are working in a university or scientific institution, it is necessary to provide the relevant document, and the reason for the need for the requested information and the type of relationship with the other study is requested.

**Comments**