

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)

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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

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

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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

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Afshar Hospital Jomhouri Boulevard. Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman 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
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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Dr. Mohammad Satayesh
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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