# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 2026

## Evaluating the effectiveness of Rosa canina L. fruit syrup on hypertension, cholesterol and anxiety In patients with hypertension A double-blind randomized clinical trial

## Protocol summary

**Study aim**

Determining the effectiveness of Rosa syrup on hypertension, cholesterol and anxiety in patients with hypertension

**Design**

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. Stratified block randomization method was used for randomization.

**Settings and conduct**

Men and women aged 35 to 65 who referred to Shahid Avini Health Center new cases of HTN who are eligible to enter the study will be completed anxiety questionnaire (Hamilton).To assess HDL and LDL, blood samples are taken. Since a healthy lifestyle is an important factor in controlling HTN, the LSQ for patients is full and excluded based on whether they are in the upper or lower third of the maximum score.Other are divided into two groups. One group receives the drug and the other placebo 10cc once a day, and the duration of the study is eight weeks. Follow-ups will be every two weeks from the beginning of treatment. Blood pressure is measured twice, five minutes apart from the dominant hand. Finally blood sample is taken for re-examination and the HQ is completed.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1. Women and men in the age 35 to 65 years 2. Systolic BP greater than or equal to 130 to 159 and diastolic BP greater than or equal to 85 to 99 mm Hg Criteria for not entering: 1- Pregnant and lactating 2- High normal pressure and grade 1 who have CVD, especially CAD or grade 4 kidney failure or diabetes that has led to organ damage, or grade 1 with chronic grade 3 kidney failure or diabetes without organ damage 3- G6PD, hemochromatosis 4- Taking drugs such as warfarin, aspirin and lithium

**Intervention groups**

They randomly receive one of the two treatments of Rosa syrup and placebo in the amount of 10cc once a day and the duration of the study is eight weeks.

**Main outcome variables**

Systolic BP Diastolic BP LDL and HDL levels Anxiety severity

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20211017052785N1**
Registration date: **2022-03-26, 1401/01/06**
Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**
Update count: **0**

**Registration date**

2022-03-26, 1401/01/06

**Registrant information**

**Name**

Mina Maarefvand

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 26 3464 3705

**Email address**

m.maarefvand@abzums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-07-06, 1401/04/15

**Expected recruitment end date**

2023-08-06, 1402/05/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluating the effectiveness of Rosa canina L. fruit syrup on hypertension, cholesterol and anxiety In patients with hypertension A double-blind randomized clinical trial

**Public title**
Evaluating the effectiveness of Rosa canina L. fruit syrup on hypertension, cholesterol and anxiety In patients with hypertension

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Men and women in the age of 35 to 65 years with high blood pressure Systolic blood pressure greater than or equal to 130 to 159 and diastolic blood pressure greater than or equal to 85 to 99 mm Hg

**Exclusion criteria:**
Pregnant and lactating women Patients with high normal blood pressure and grade 1 who have cardiovascular disease, especially coronary artery disease or grade 4 kidney failure or diabetes that leads to organ damage or grade 1 with chronic kidney failure grade 3 or diabetes without organ damage or organ damage due to high blood pressure The above is already specified in them. G6PD, hemochromatosis Taking medications such as warfarin, aspirin and lithium

**Age**
From **35 years** old to **65 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Participants are divided into two groups by stratified block randomization, one group receives medication and the other receives placebo.Patients (after completing the lifestyle questionnaire and excluding people who receive the upper or lower third of the score) are divided into six groups based on the score of the lifestyle questionnaire, and each of them by designing 4 blocks and selecting blocks through the lottery, they receive one of two drug or placebo options, respectively, based on the block plan.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The drugs used in the present study were prepared by the second executor, which has nothing to do with sampling and prescribing drugs. It is prepared in anonymous packs and given to the researcher. The contents of the packs remain completely confidential and will only be available to the drug manufacturer. The name of the medicine will be given to the personnel when the side effects of the medicine occur. The placebo is prepared by considering the necessary standards in color, smell, taste, shape, etc.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Alborz University of Medical Sciences

**Street address**
45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology

**City**
Karaj

**Province**
Alborz

**Postal code**
3198764653

**Approval date**
2022-02-26, 1400/12/07

**Ethics committee reference number**
IR.ABZUMS.REC.1400.350

## Health conditions studied

### 1

**Description of health condition studied**
HTN

**ICD-10 code**
I10

**ICD-10 code description**
Essential (primary) hypertension

## Primary outcomes

### 1

**Description**
Systolic and diastolic blood pressure

**Timepoint**
First visit and then every two weeks until the eighth week
**Method of measurement**
Digital sphygmomanometer

**2**

**Description**
Blood HDL and LDL levels
**Timepoint**
Beginning and end of the trial
**Method of measurement**
Laboratory experiment

**3**

**Description**
Severity of anxiety
**Timepoint**
Beginning and end of the trial
**Method of measurement**
Hamilton anxiety questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: To prepare Rosa syrup (according to USP 39 – NF 34, Second Supplement Commentary, June 1, 2016): 100 grams of washed Nastaran fruit soaked in 1000 cc of water, after 3 hours, boiled for 10 minutes and cooled in the laboratory. After cooling, we filter the contents of the container with a filter and concentrate the obtained product using a benmary. From 100 grams of Nastaran fruit, 8 grams of dry extract obtained from the extract obtained, 5 grams of it are brought to 100 grams using USP syrup making model with 7.66 grams of honey and 28.5 grams of water. The resulting syrup is poured into 120 cc sterile jars and sealed and sterilized by autoclave. The designed label is then installed and delivered for clinical trial. The raw materials of the medicine are prepared from reliable sources and the initial evaluation of its quality is done.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Placebo is prepared by considering the necessary standards in color, smell, taste, shape, etc. It will be consumed at a rate of 10cc once a day, half an hour before lunch and for a period of eight weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Avini Comprehensive Health Center
**Full name of responsible person**
Dr. Mina Maarefvand
**Street address**
Kianmehr, Amir Kabir Boulevard, Azadi Boulevard
**City**
Karaj
**Province**
Alborz
**Postal code**
2633204636
**Phone**
+98 26 3320 4636
**Email**
dr.m.maarefvand@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Karaj University of Medical Sciences
**Full name of responsible person**
Dr. Hatem Godini
**Street address**
45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology
**City**
karaj
**Province**
Alborz
**Postal code**
3198764653
**Phone**
+98 26 3464 3774
**Email**
Research@abzums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Karaj 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**
Karaj University of Medical Sciences

**Full name of responsible person**
Dr. Mina Maarefvand

**Position**
Non-faculty specialist physician

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

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45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology

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**Postal code**
3198764653

**Phone**
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**Email**
dr.m.maarefvand@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Karaj University of Medical Sciences

**Full name of responsible person**
Dr. Mina Maarefvand

**Position**
Non-faculty specialist physician

**Latest degree**
Ph.D.

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**Email**
dr.m.maarefvand@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Karaj University of Medical Sciences

**Full name of responsible person**
Dr. Mina Maarefvad

**Position**
Non-faculty specialist physician

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

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**Email**
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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**
Part of the data, such as information about the main consequences, can be shared by inserting it in the study article.

**When the data will become available and for how long**
Access period starts 8 months after the results are published

**To whom data/document is available**
Only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
Using data to advance scientific goals

**From where data/document is obtainable**
Dr. Maarefvand dr.m.maarefvand@gmail.com

**What processes are involved for a request to access data/document**
Send the request for information via the announced gmail and the party will receive a response within a maximum of two weeks.

**Comments**