Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
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Postal code
2633204636
Phone
+98 26 3320 4636
Email
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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
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Phone
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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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Contact

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Position
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Person responsible for updating data

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Position
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Ph.D.

Other areas of specialty/work
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Email
dr.m.maarefvand@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
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