

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Assess the effect of Cretaegus herbal medicine on control of hypertension patients

Protocol summary

Study aim

1. Assess the effect of Cretaegus on control of hypertension
2. Assess the effect of Cretaegus on control of hypertension base on dose of consumption of hypertension drugs
3. Assess the effect of Cretaegus on control of hypertension base on the number of drugs in order to control of hypertension
4. Assess the effect of Cretaegus on control of hypertension base on stage of hypertension

Design

Two arm parallel groups randomized trial with blinded outcome and assessment. Phase 3 with 110 participators will start. Randomization was was centralized and computerized with concealed randomization sequence carried out at an external site.

Settings and conduct

The study will be done on hypertension patients refer to Imam Hossien hospital of Shahroud. After grouping and beginning of treatment protocol, patients will be assessed at end of 8,10,12,14,16 week. Also, because we use pocket for grouping, analyzer and nurse who assess the patients are blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Primary hypertension patients (systolic pressure more than or equal 140 mmHg and/or diastolic pressure more than or equal 90 mmHg) that their systolic pressure less than 180 mmHg and diastolic pressure lower than 110 mmHg) 2. Patients written consent form
Exclusion criteria: 1. Patients do not tend to continue the project 2. Secondary hypertension patients 3. Patients with chronic kidney disease 4. Patients with high usage dose of cortone 5. Pregnant patients 6. Usage of digoxin 7. Usage of antiarrhythmic drugs (class II) 8. Usage of enoxaparin, warfarin, heparin

Intervention groups

First group: Crataegus drop will be prescribed three times a day and each time 20 drops for 4 month with their hypertension drugs. second group: they only use in accordance to hypertension treatment protocol.

Main outcome variables

Blood pressure control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046101N2**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Erfan Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3226 4711

Email address

kazemi.e@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assess the effect of Cretaegus herbal medicine on control of hypertension patients

Public title

Assess the effect of Cretaegus on hypertension

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary hypertension patients (systolic pressure is more or equal to 140 mmHg and/or diastolic pressure is more or equal to 90 mmHg) that their systolic pressure less than 180 mmHg and diastolic pressure lower than 110 mmHg) Patients written consent form

Exclusion criteria:

Patients do not tend to continue the project Secondary hypertension patients Patients with chronic kidney disease Patients with high usage dose of cortone Pregnant patients Usage of digoxin Usage of antiarrhythmic drugs (class II) Usage of enoxaparin, warfarin, heparin

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

We used block randomization (with 4 letters). Because , patients will be entered in the study gradually and having equal sample size in both groups. Therefore, 24 block that included of 4 letters will be made. The desired sequence have been made by this website (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>)

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the nurse who measure the blood pressure and statistical counsellor are blinded. In this regard, we use 28 closed pockets which type of group determined inside of them. we number on each pockets. After, basic information of the patients written, a pocket will be opened and their type of group will be determined.

Placebo

Not used

Assignment

Parallel

Other design features

We do not use any placebo in this study

Secondary Ids

empty

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

Ethics committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, 7 Tir square

City

Shahroud

Province

Semnan

Postal code

3614773943

Approval date

2022-03-09, 1400/12/18

Ethics committee reference number

IR.SHMU.REC.1400.135

Health conditions studied**1****Description of health condition studied**

Essential hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Blood pressure control

Timepoint

At the beginning of the study, at end of 8, 10, 12, 14, 16 weeks

Method of measurement

Digital pressure gauge

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

Reducing the number of hypertension medicine

Timepoint

At end of 8, 10 12, 14 16 weeks

Method of measurement

The number of hypertension drugs are used to control blood pressure.

2

Description

Reducing consumed dose of the drugs

Timepoint

At the end of 8, 10, 12, 14, 16 weeks

Method of measurement

The amount of prescribed drug base on milligram per kilogram

Intervention groups

1

Description

Intervention group: The group used Cretaegus drop with hypertension drugs. They have to use the drop three times a day and each time include of 20 drops till 4 months . The drop is produced by Iran Darouk company

Category

Treatment - Drugs

2

Description

Control group: This group just use their common hypertension drugs to control their blood pressure for four months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital of Shahroud

Full name of responsible person

Erfan Kazemi

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Student research committee of medical university, 7 Tir square, Shahroud

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

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Grant name

Grant code / Reference number

99138

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Erfan Kazemi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available