Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The clinical trial of the effect of crataegus monogyna on hypertension and associated sleep disorders

Protocol summary

Study aim
Determine the effects of Crataegus monogyna on Hypertension

Design
By using random numbers table, patients are divided in two groups ,case and control. All participants and researchers are blind in this study, coding of medicine and placebo are under the responsibility of a statistical adviser who is not blind.

Settings and conduct
Dry extract of Crataegus Monogyna with a concentration of 10% relative to 100 gr of the plant, has been standardized 250mg per capsule at the school of pharmacy of Shahid Behest university of Medical Sciences.The drug is given one capsule every 12 hours for 60 days to volunteer patient with hypertension(the patients refer to special clinic Zanjan university of Medical science) Control group:Placebo in the control group contains starch corn which is provided in capsules and boxes of the same intervention group.the placebo is given one capsule every 12 hours for 60 days to volunteer patient with hypertension(the patients refer to special clinic Zanjan university of Medical science) All participations and researchers are blind in this study, coding of medicine and placebo are under the responsibility of a statistical adviser who isnot blind.

Participants/Inclusion and exclusion criteria
Informed study participation, age 35 to 60,Hypertension , continuing heart medications, prescribed by cardiologist. Pregnancy, Breast feeding, Malignancy, Sever hypertension, Chronic Inflamatory diseas, Renal failure, Sever liver disease, Acute infectious disease, Secondary hypertension, Age less than 35 and older than 60, Taking digoxin, Arryhthmia

Intervention groups
60 Patients have Hypertension at 35 to 60 years that conditions have in plan.30 person take placebo and 30 person take drug

Main outcome variables
1-Quality of sleep in the Pittsburgh Questionnaire 2- Systolic blood pressure 3- FBS,BUN,Cr,Hb, ALT,AST, TG

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180225038859N1**
Registration date: **2018-05-26, 1397/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-26, 1397/03/05**
Update count: **0**

Registration date
2018-05-26, 1397/03/05

Registrant information

Name
masumeh abbasi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 6689 3256

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-07-23, 1397/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The clinical trial of the effect of crataegus monogyna on hypertension and associated sleep disorders

Public title
Effect of Crataegus Monogyna in hypertension and associated sleep disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hypertensive patient that they didn't respond to medical treatment

Exclusion criteria:
Pregnancy Breast feeding Malignancy Sever hypertension Chronic Inflamatory diseas Renal failure Sever liver disease Acute infectious disease Secondary hypertension Age less than 35 and older than 60 Taking digoxin Arryhthmia

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
By using random numbers table patients are divided in two 30 person intervention or control groups

Blinding (investigator's opinion)
Triple blinded

Blinding description
All participations and researchers are blind in this study, coding of medicine and placebo are under the responsibility of a statistical adviser who is not blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Science

Street address
First of Jomhuri Blvd , Azadi Sq

City
Zanjan

Province
Zanjan

Postal code
۴۵۱۵۴

Approval date
2018-03-06, 1396/12/15

Ethics committee reference number
IR.ZUMS.REC.1396.301

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
Quality of sleep in the Pittsburgh Questionnaire

Timepoint
Measure the quality of sleep at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement
Pittsburgh sleep quality questionnaire in patients with hypertension

2

Description
Systolic blood pressure

Timepoint
Measure the Blood Pressure at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement
Blood Pressure Device

Secondary outcomes

1

Description
Fasting blood sugar test

Timepoint

Measure the FBS at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement

Blood Test

2

Description

Blood Urea Nitrogen

Timepoint

Measure the BUN at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement

Blood Test

3

Description

Hemoglobin

Timepoint

Measure the Hb at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement

Blood Test

4

Description

Creatinine

Timepoint

Measure the Cr at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement

Blood Test

5

Description

ALT and AST

Timepoint

Measure the ALT and ASTbat the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement

Blood Test

6

Description

Triglyceride

Timepoint

Measure the TG at the beginning of study(before intervention)and two week after taking the Crataegus Monogyna

Method of measurement

Blood Test

Intervention groups

1

Description

Intervention group: Dry extract of Crataegus Monogyna with a concentration of 10% relative to 100 gr of the plant, has been standardized 250mg per capsule at the school of pharmacy of Shahid Behest university of Medical Sciences.The drug is given one capsule every 12 hours for 60 days to Voluptuous patient with hypertension.

Category

Treatment - Drugs

2

Description

Control group: Placebo in the control group contains starch corn which is provided in capsules and boxes of the same intervention group at the school of Pharmacy of Shahid Behest university of Medical Sciences.The placebo is given one capsule every 12 hours for 60 days to volunteer patients with hypertension

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Clinic in Zanjan University of Medical Sciences

Full name of responsible person

Masumeh Abbasi

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7Tired St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Masume Abbasi
Position
Ph.D Student of Iranian Medicin
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
Undecided - It is not yet known if there will be 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

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

Data Dictionary

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