Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of Onopordon Acanthium Seed on Primary Hypertension Reduction in Patients under Treatment by Losartan

Protocol summary

Summary

The aim of this study is investigating the effect of Onopordon Acanthium seed on primary hypertension reduction in patients under treatment by losartan. The statistical sample of the study includes 20-25 patients aged 30-60 suffering from primary hypertension in Imam Khomeini Hospital or Amir-Alam Hospital of Tehran University of Medical Sciences who are under treatment by Losartan but still their blood pressure is greater than or equal to 140/90 mmHg. These patients must not have a background of malignant hypertension, heart disease. They also must not suffer from side effects of end organ disorder due to blood pressure increase. The patients take 50 mg Losartan on a daily basis. In addition to 4 capsules containing Onopordon Acanthium extract for two months. Patients are visited every two weeks. At the end of two months, data will be recorded and analysed at the end of the research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020712391N1**
Registration date: **2013-04-14, 1392/01/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-14, 1392/01/25

Registrant information

Name

Roshanak Ghods

Name of organization / entity

Tehran University of Medical Sciences - Faculty of Traditional Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 7750 4066

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Onopordon Acanthium Seed on Primary Hypertension Reduction in Patients under Treatment by Losartan

Public title

Investigating the Effect of Onopordon Acanthium Seed on Primary Hypertension Reduction in Patients under Treatment by Losartan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Aged between 30 and 60; SBP>= 140; DBP >= 90 mmHg; Patient under treatment by Losartan (50 mg); Exclusion Criteria: Existence of malignant hypertension, i.e. blood pressure higher than 200/140 mmHg which needs multi-drug treatment or emergency IV drug infusion to control blood pressure; History of secondary hypertension ; Existence of end organ

damages (EOD); Sudden increase of blood pressure to greater than 15 mmHg at any time during the study; Existence of any kind of cardiac arrhythmias; Symptomatic valvular heart diseases (except mitral valve prolapse); Liver function disorders; Pregnancy and lactation; Cured or uncured malignancy during the last 5 years; Serum potassium >5.2 or <3.5 mEq/L in the first visit; Drug or alcohol usage background; Any kind of disorder (medical or surgical) which can interfere the study

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Institue for Islamic and Complementary Medicine

Street address
No. 9, First Pirnia Allay, North Lale-zaar St. Jomhoori Eslami St., Tehran

City
Tehran

Postal code

Approval date
2012-10-09, 1391/07/18

Ethics committee reference number
ط/م/26پ/732

Health conditions studied

1

Description of health condition studied
Primary hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic Blood Pressure

Timepoint
Beginning of the project, End of the second week, end of the fourth week, end of the sixth week, end of the eighth week

Method of measurement
Measuring by mercury sphygmomanometer in millimetres of mercury (mmHg)

2

Description
Diastolic Blood Pressure

Timepoint
Beginning of the project, End of the second week, end of the fourth week, end of the sixth week, end of the eighth week

Method of measurement
Measuring by mercury sphygmomanometer in millimetres of mercury (mmHg)

Secondary outcomes

empty

Intervention groups

1

Description
All patients in interfering group take 50mg Losartan and also a capsule containing Onopordon Acanthium seeds extract orally once a day.

Category
Treatment - Drugs

2

Description
All patients in control group, take 50mg Losartan and also placebo which is designed this study orally once a day.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Dr. Manoochehr Gharooni
Street address
Angiography section, Imam Khomeini Hospital, Keshavarz Blvd., Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Amir Alam Hospital
Full name of responsible person
Dr. Manoochehr Gharooni
Street address
C.C.U. Section, Amir-Alam Hospital, Sa'di St., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dariush Mahmoodi
Street address
Office of Vice Chancellor for Research, Third floor, Faculty of Traditional Medicine, Behesht St., Vahdat Eslami St. (South Hafiz), Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Traditional Medicine and Pharmacy Research Center
Full name of responsible person
Dr.Tahmineh Akbarzade
Street address
Traditional Medicine and Pharmacy Research Center,Tehran University of Medical Sciences,Tehran,Iran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Traditional Medicine and Pharmacy Research Center
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Phd candidate
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty