

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 \geq 140; DBP \geq 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 Institute 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

732/پ26/م/ط

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 addressAngiography section, Imam Khomeini Hospital,
Keshavarz Blvd., Tehran**City**

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2**Recruitment center****Name of recruitment center**

Amir Alam Hospital

Full name of responsible person

Dr. Manoochehr Gharooni

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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

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Faculty of Traditional Medicine, Behesht St., Vahdat
Eslami St. (South Hafiz), Tehran**City**

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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

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

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Traditional Medicine and Pharmacy Research

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Sciences, Tehran, Iran**City**

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

Dr.Roshanak Ghods

Position

Phd candidate

Other areas of specialty/work**Street address**Behesht Clinic, Behesht St., Vahdat-e Eslami st.
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Tehran University of Medical Sciences

Full name of responsible person

Dr. Manoochehr Gharooni

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Cardiologist

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Person responsible for updating data

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Full name of responsible person

Dr.Roshanak Ghods

Position

Phd candidate

Other areas of specialty/work

Street address

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City

Tehran

Postal code

Phone

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