Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The Effect of Spironolactone as Monotherapy on Systolic and Diastolic Blood Pressure in Patients with Essential Hypertension

Protocol summary

Summary

This study has been designed to assess the effect of spironolactone as monotherapy on systolic and diastolic blood pressure in patients suffering from essential hypertension referred to the Health Heart House. In this randomized controlled clinical study, 40 people who are referred to Shiraz Heart House and suffer from essential hypertension according to ambulatory blood pressure holter monitoring have been selected. Inclusion criteria are: systolic blood pressure more than 135 mmhg or diastolic blood pressure more than 85 mmhg. Exclusion criteria are: serum creatinine more than 2 mg/dl؛ serum potassium more than 5 meq/l؛ renal or other endocrine diseases and diabetes. These persons have randomly been divided into experiment group (20 persons) receiving Spironolactone and control group (20 persons) who receive placebo. The experiment group has been given one tablet of Spironolactone daily for one month and the control group has been given one tablet of placebo daily for one month. Also low salt and low fat diet will recommend to all patients.At the end, ambulatory blood pressure holter monitoring will be done again. Finally systolic and diastolic blood pressure before and after intervention will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502011525N6**
Registration date: **2015-03-14, 1393/12/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-14, 1393/12/23

Registrant information

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Mohammad Javad Zibaeenezhad
Name of organization / entity
Cardiovascular Research Center, Shiraz University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spironolactone as Monotherapy on Systolic and Diastolic Blood Pressure in Patients with Essential Hypertension

Public title

The Effect of Spironolactone in Treatment of Essential Hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion crireria: systolic blood pressure more than 135 mmhg; diastolic blood pressure more than 85 mmhg

Exclusion criteria: serum creatinine more than 2 mg/dl; serum potassium more than 5 meq/l; renal or other endocrine diseases; diabetes

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand St, Shiraz

City
Shiraz

Postal code
7134814336

Approval date
2014-12-14, 1393/09/23

Ethics committee reference number
CP-P-9354-5874

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
Systolic blood pressure

Timepoint
Before intervention and 1 month after intervention

Method of measurement
Ambulatory 24 hour blood pressure holter monitoring

2

Description
Diastolic blood pressure

Timepoint
Before intervention and 1 month after intervention

Method of measurement
Ambulatory 24 hour blood pressure holter monitoring

Secondary outcomes

1

Description
Level of serum potassium

Timepoint
Before Intervention and One Month After Intervention

Method of measurement
Biochemical Measurements on Blood Sample

Intervention groups

1

Description
Intervention group: Spironolactone, 25 mg oral tablet, one tablet daily for one month

Category
Treatment - Drugs

2

Description
Control group: placebo, oral tablet, one tablet daily for one month

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Cardiovascular Research Center of Shiraz University of Medical Sciences

Full name of responsible person
Amirabbas Sadeghi (resident of cardiology)

Street address
Cardiovascular Research Center, Khalili St, Shiraz

City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Midical Sciences
Full name of responsible person
Mrs. Hoghooghi
Street address
Cardiovascular Research center, Khalili St, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Midical Sciences
Proportion provided by this source
100
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
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Phone
Fax
Email
Web page address

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