

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of “Aloe vera” on the control of essential hypertension in patients under treatment with Losartan; a double-blind randomized clinical trial

Protocol summary

Summary

In this double-blind randomized controlled trial, patients with uncontrolled hypertension (blood pressure equal to or more than 110/80 mmHg) who are under treatment with 50 mg Losartan and presented to the cardiology clinics of Zanjan University of Medical Sciences and met our criteria will be included. The calculated sample size for this study is 40 patients in total (two groups with 20 individuals each). After recording the baseline demographic and clinical characteristics of the patients, particularly the baseline blood pressure and performing the routine blood tests, the patients will be randomized to receive either Aloe vera extract (250 mg capsules daily for 8 weeks) or placebo. Before the initiation of the experiment, the individual's constitutional nature of the patients will be evaluated using a questionnaire and will be checked up by three traditional medicine specialists. Every 2 weeks the patients will be visited for the measurement of the blood pressure and will be checked for the development of any side effects and the effect of the treatment on their constitutional nature. Finally, the changes of blood pressure will be compared between the study groups and we will decide about the effect of Aloe vera on the blood pressure of the patients. Primary outcome of the study is the change in the blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040827276N1**

Registration date: **2016-06-02, 1395/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-02, 1395/03/13

Registrant information

Name

Anahita Heidari

Name of organization / entity

Zanjan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of “Aloe vera” on the control of essential hypertension in patients under treatment with Losartan; a double-blind randomized clinical trial

Public title

The effect of “Aloe vera” on the control of essential hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria All women and men; presenting with uncontrolled hypertension who present to the cardiology clinics affiliated to the Zanjan University of Medical Sciences; aged 30-70; with systolic blood pressure greater than or equal to 140 and diastolic blood pressure greater than or equal to 90 mg; using 50 mg losartan for at least 6 weeks. Exclusion Criteria: hypertension, greater than or equal to 180/110 mgHg which needs multi-drug treatment or emergency injection to control the blood pressure; Diagnosis of secondary blood pressure, e.g. Hyperaldosteronism, pheochromocytoma, Cushing syndrome, renal artery stenosis; Symptoms of End organ damage such as renal failure, congestion heart failure, myocardial infraction, cerebrovascular incidences within six months before the research starts; Sudden increase in blood pressure greater than 15mmHg in any time during the research (necessary to mention, if with increase lesser than 15 mmHg the blood pressure of the case is greater than or equal to 180/110 mmHg, he will be discarded from the study and, then, will be referred to a cardio-vascular specialist); Various Heart arrhythmias (such as blocks grades 2 and 3); Symptomatic heart valve diseases (except Mitral Valve prolapse); Renal or hepatic failure (Liver cirrhosis, Chronic active Hepatitis or autoimmune Hepatitis); Pregnancy and breastfeeding; Serum Potassium greater than 5 or less than 3.5 meq/L in the first visit; Any sort of disorder/failure (either medical or surgical), from researcher's point of view, which can intervene the research; Taking drugs that influence blood pressure such as NSAIDs, CORTICOSTEROIDS, Oral contraceptives; Psychological disorders such as anxiety, depression, obsession, or taking Psychiatric drugs

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

1-2

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

zanjan medical university

Street address

medical univesity - zanjan

City

zanjan

Postal code

Approval date

2016-04-12, 1395/01/24

Ethics committee reference number

ZUMS.REC.1395.21

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

blood pressure

Timepoint

one baselinemeasurement and 4 times follow up measurement every 2 weeks

Method of measurement

mmHg with sphygomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Capsules containing aloe vera extract for 8 weeks

Category

Treatment - Drugs

2

Description

Capsules containing 250 mg Lactose for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiology clinics affiliated to Zanjan university of medical science

Full name of responsible person

Anahita Heidari

Street address

Ayatollah Mousavi educational & treatment center, gavazang road zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

Dr. Soghrat Faghihzadeh

Street address

Headquarter of medical science, deputy research & technology, Jomhori street, Azadi sq, Zanjan

City

Zanjan

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 Science

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**Name of organization / entity**

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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