

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24 3344 0301

###### Email address

doc.heidari@zums.ac.ir

##### 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Anahita Heidari

**Position**

PhD student of traditional medicine

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Hasan Ahangar

**Position**

Cardiologist

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## Person responsible for updating data

#### Contact

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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*