

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Therapeutic effects of losartan in nonalcoholic steatohepatitis

#### Protocol summary

##### Study aim

Proof of Losartan Effect on Improvement of Laboratory Indices and Non-Alcoholic Staphylococcus aureus

##### Design

In this study, 42 patients with non-alcoholic steatohepatitis who are eligible to enter the study, who are referred to Gastroenterology and Internal Medicine Clinic of Amir Al-Momenin Hospital and Imam Reza Arak Clinic, are selected. Participants are randomly divided into intervention and control groups and assigned a code to hide the intervention group of each participant.

##### Settings and conduct

The study was performed on patients with non-alcoholic fatty liver who referred to the internal and gastrointestinal clinic of Amirmomenin Hospital and Imam Reza city of Arak. They were randomly assigned to one of the control and case groups. The case group was treated with losartan and the control group to be treated with placebo, and in order to hide the intervention, each participant is assigned a code.

##### Participants/Inclusion and exclusion criteria

Patients with non-alcoholic steatohepatitis who have not had other causes of hepatic steatosis, who have high blood pressure, have not received angiotensin-blocking drugs and ACE inhibitors over the past year, and have not been resistant to hypertension.

##### Intervention groups

The losartan group will receive a dose of 50 mg per day and will be given to patients in the placebo control group for 6 months.

##### Main outcome variables

AST, ALT, ALKP, liver ultrasound

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161210031316N2**

Registration date: **2018-02-13, 1396/11/24**

Registration timing: **retrospective**

Last update: **2018-02-13, 1396/11/24**

Update count: **0**

##### Registration date

2018-02-13, 1396/11/24

##### Registrant information

###### Name

Moosa Abdollahi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3639

###### Email address

m.abdollahi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

11017000

##### Expected recruitment start date

2016-11-01, 1395/08/11

##### 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

Therapeutic effects of losartan in nonalcoholic steatohepatitis

##### Public title

Nonalcoholic fatty liver treatment

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Non-alcoholic steatohepatitis and liver enzymes are based on indicators of liver function and ultrasound Age over 18 years

### Exclusion criteria:

alcohol intake of angiotensin receptor antagonists use of angiotensin converting enzyme inhibitors resistance-resistant hypertension Uncontrolled Diabetes hypotension serious interactions with other patient medications other causes of liver steatosis

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **42**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In a simple random method, using a flip the coin, they enter one of the groups or control.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

For both groups, placebo capsules with similar characteristics will be used, and none of the patients will be aware of the two groups of received drugs, and the two groups will be followed up and examined and the investigator will be aware of the patient's drug intake.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

meydan e basij

##### City

Arak

##### Province

Markazi

##### Postal code

38481-7-6941

## Approval date

2016-08-22, 1395/06/01

## Ethics committee reference number

IR.ARAKMU.REC.1395.203

## Health conditions studied

### 1

#### Description of health condition studied

NASH

#### ICD-10 code

K75.81

#### ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

## Primary outcomes

### 1

#### Description

Serum creatinin

#### Timepoint

Measurement of serum creatinine at baseline (before intervention) and 7 days and 1.3.6 months after initiation of losartan administration

#### Method of measurement

by Laboratory

### 2

#### Description

Serum potasium

#### Timepoint

Serum potassium measurements at the beginning of the study (before intervention) and 7 days and 1.3.6 months after the start of losartan administration

#### Method of measurement

by Laboratory

### 3

#### Description

Serum Alkaline phosphatase

#### Timepoint

Measurement of serum alkaline phosphatase at baseline (before intervention) and 3.6 months after initiation of losartan administration

#### Method of measurement

by Laboratory

### 4

#### Description

Serum Alanine aminotransferase

#### Timepoint

Measurement of serum alanine aminotransferase at baseline (before intervention) and 3.6 months after initiation of losartan administration

#### Method of measurement

by Laboratory

## 5

### **Description**

Serum Aspartate aminotransferase

### **Timepoint**

Measurement of serum aspartate aminotransferase at baseline (before intervention) and 3.6 months after initiation of losartan administration

### **Method of measurement**

by Laboratory

## 6

### **Description**

Blood pressure

### **Timepoint**

Blood pressure measurement at the beginning of the study (before the intervention) and 1,2,3,4,5,6 months after the start of losartan administration

### **Method of measurement**

Barometer

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### **Description**

Body Mass Index

### **Timepoint**

Measuring the body mass index at the beginning of the study (before the intervention) and 3.6 months after starting the administration of losartan

### **Method of measurement**

Meter , Balance

## 8

### **Description**

Liver ultrasound indices

### **Timepoint**

Measurement of liver ultrasonography at the beginning of the study (before the intervention) and 3.6 months after the start of administration of losartan

### **Method of measurement**

Sonography

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: Placebo for 6 month

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 1: Losartan (abidi: lostar) 25 mg daily for 6 month

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Amiralmomenin Hospital

##### **Full name of responsible person**

Moosa Abdollahi

##### **Street address**

Amiralmomenin Hospital, Sardasht Square

##### **City**

Arak

##### **Province**

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##### **Postal code**

3848176941

##### **Phone**

+98 86 3417 3630

##### **Email**

moosadr@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr Mohammad Arjmandzadegan

##### **Street address**

Sardasht Square, Arak Medical Faculty, Department of Research and Research and Information Technology

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##### **Province**

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##### **Email**

arjomandzadegan@arakmu.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

-

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Arak University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic  
**Category of foreign source of funding**  
empty  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Azim Forozan  
**Position**  
Gastroenterologist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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### Web page address

## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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moosadr@gmail.com  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

In this study, after unidentification, all the study data, including demographic information, paraclinical outcomes and the results of the study, including the results of tests and paraclinic and the treatment complications, will be published.

### When the data will become available and for how long

Concurrent with the publication of the study results

### To whom data/document is available

Researchers in Medical Sciences

### Under which criteria data/document could be used

For further research, researchers will be able to access data from the research vice president.

**From where data/document is obtainable**

Supervisor

**What processes are involved for a request to access data/document**

First, you must contact the supervisor by email, and then the supervisor handles the request with the deputy investigator and, if approved, provides the supervisor or documentary master with the requester.

**Comments**