

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Effects of losartan drug on liver function tests in patients with non alcoholic steatohepatitis (NASH)

#### Protocol summary

##### Summary

Objectives: Determine the effect of losartan on liver function tests in patients with non alcoholic steatohepatitis (NASH) . Design: Prospective randomized clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: One hundred patients, with age 18-60 yr ; candidates for the treatment of chronic hypertension in Sina Hospital during 2016-2017, were included. Patients were randomized into two groups of 50 each, using a table of random numbers. Intervention: Intervention group , patients received oral tablets Losartan 50 mg daily for six months and control group , patients received oral tablets Amlodipine 5 mg for six months. Main outcome measures (variables): Liver function tests (Aspartate aminotransferase; Alanine aminotransferase; Alkaline phosphatase); Triglycerides; cholesterol. In each group, drug type are coded by individual not aware of the research process.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016060628305N1**

Registration date: **2016-08-14, 1395/05/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-08-14, 1395/05/24

##### Registrant information

##### Name

Alireza Sharifi

##### Name of organization / entity

Sina Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8533

##### Email address

sharifra@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences and Health Services

##### Expected recruitment start date

2016-07-26, 1395/05/05

##### Expected recruitment end date

2017-02-18, 1395/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of losartan drug on liver function tests in patients with non alcoholic steatohepatitis (NASH)

##### Public title

Effects of losartan tablets in the treatment and modification of liver function in patients with non-alcoholic fatty liver

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age > 18 years old; Chronic hypertension. Exclusion criteria: Viral hepatitis; Human immunodeficiency virus positive; Pregnancy; Diabetes; Daily alcohol consumption; Use of drugs affecting liver enzymes in the last 6 months; A history of liver disease; Kidney disease; Chronic debilitating disease; Gastrointestinal bleeding active in the last 6 months ;

Consumption previous and current weight loss or lipid drugs; Anti-TNF $\alpha$ ; Stimulant drugs insulin; Metformin ; Vitamin E; Pentoxifylline

## Age

From **98 years** old to **56 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences and Health Services

##### Street address

Poursina St.

##### City

Tehran

##### Postal code

#### Approval date

2016-07-09, 1395/04/19

#### Ethics committee reference number

IR.TUMS.REC.1395.2760

## Health conditions studied

### 1

#### Description of health condition studied

Liver function in non alcoholic steatohepatitis (NASH) patients

#### ICD-10 code

R94.5

#### ICD-10 code description

Abnormal results of liver function studies

## Primary outcomes

### 1

#### Description

Aspartate aminotransferase

#### Timepoint

Before starting treatment, every two months to six months after treatment

#### Method of measurement

Blood sample

### 2

#### Description

Alanine aminotransferase

#### Timepoint

Before starting treatment, every two months to six months after treatment

#### Method of measurement

Blood sample

### 3

#### Description

Alkaline phosphatase

#### Timepoint

Before starting treatment, every two months to six months after treatment

#### Method of measurement

Blood sample

### 4

#### Description

Triglyceride

#### Timepoint

Before starting treatment, every two months to six months after treatment

#### Method of measurement

Blood sample

### 5

#### Description

Cholesterol

#### Timepoint

Before starting treatment, every two months to six months after treatment

#### Method of measurement

Blood sample

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the intervention group, Losartan 50 mg tablet taken orally, once a day for six months

**Category**

Treatment - Drugs

**2****Description**

In the control group, Amlodipine 5 mg tablets orally, once a day for six months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Alireza Sharifi MD.

**Street address**

Imam Khomeini st.

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

**Full name of responsible person**

Shahin Akhuzadeh P.H.D

**Street address**

Poursina St.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

**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**

Sina Hospital

**Full name of responsible person**

Alireza Sharifi MD.

**Position**

Subspecialty of Gastroenterology and Hepatology

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**Fax****Email**

sharifra@tums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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sharifra@tums.ac.ir

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Statistical Analysis Plan**

**Data Dictionary**

*empty*