Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 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-TNFα; 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 Akhunzadeh 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
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Subspecialty of Gastroenterology and Hepatology
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Person responsible for updating data

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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