Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Amiralmomenin 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)

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+98 86 3417 3639

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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

7

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
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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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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

Internal Medicine

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Internal medicine resident

Latest degree

Medical doctor

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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