

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

: Investigation Effect of losartan on improving liver function testes in NAFLD patients (Non Alcoholic Fatty Liver Disease)

Protocol summary

Study aim

Evaluation of the effects of losartan on the improvement of liver function tests in Non Alcoholic Fatty Liver Disease (NAFLD) patients.

Design

Two arm parallel group, double blind, randomised, controlled clinical trial design of 328 patients

Settings and conduct

patients who referred to Internal medicine Clinic of Imam Hossein Hospital of Tehran that diagnosed non alcoholic fatty liver disease (NAFLD), with ultrasound and aspartate transaminase (AST) > 30 and alanine transaminase (ALT) > 40 and they have including criteria or dose not have excluding criteria enrolled. patients take drugs for 12 weeks. physician and who packaged drugs and patients are blind. drugs in both group have the same size and same shape and same package.

Participants/Inclusion and exclusion criteria

Inclusion criteria; age of 20 to 80 years, pre hypertensive (i.e. systolic blood pressure (SBP): 120 to 139 mmHg, and diastolic blood pressure (DBP): 80 to 89 mmHg, diagnosed with Non Alcoholic Fatty Liver Disease (NAFLD) based on ultrasound findings, liver enzymes as AST > 30 IU/L and ALT > 40 IU/L. Exclusion criteria; positive viral hepatitis markers, positive Anti Mitochondrial Antibody (AMA) and Anti Nucleotide Antibody (ANA), history of alcohol abuse, renal insufficiency, hypertension, pregnancy, cirrhosis, toxic hepatitis, treated with Angiotensin Converting Enzyme inhibitor (ACEi) or Angiotensin 2 Receptor Blockers or thiazolidinedione.

Intervention groups

Tablet Losartan 25 mg twice a day for intervention group. Placebo for control group that as the same intervention group.

Main outcome variables

blood pressure, FBS, aspartate transaminase (AST), alanine transaminase (ALT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039283N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **retrospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

meghdad sedaghat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 7168

Email address

sedaghat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-02, 1396/09/11

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2020-10-21, 1399/07/30

Scientific title

: Investigation Effect of losartan on improving liver function testes in NAFLD patients (Non Alcoholic Fatty Liver Disease)

Public title

Investigation Effect of losartan NAFLD patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with pre hypertension and fatty liver

Exclusion criteria:

history of other liver diseases except fatty liver

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **250**

Actual sample size reached: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

We used block randomization method.each block size was 2 by 2, and in total 16 blocks were considered.the sequences for packages within each block were:AABB_BBAA_ABBA_BAAB_ABAB_BABA .then each were marked from 1 to 6 as above.After that the packages within blocks were sequentially numbered from 1 to 64.

Blinding (investigator's opinion)

Double blinded

Blinding description

The sample recipient and patient are not aware of the type of drug.the lab that received samples isn't aware of type of drug. losartan and placebo are same shape.and they pack same.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

koodakyari street.velenjak

City

Tehran

Province

Tehran

Postal code

1234569871

Approval date

2019-02-09, 1397/11/20

Ethics committee reference number

IR.sbm.u.msp.REC.1397.325

Health conditions studied

1

Description of health condition studied

NAFLD

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

liver functions tests

Timepoint

liver function tests before losartan and 12 weeks after losartan

Method of measurement

laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: losartan 25 mg twice a day for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo 25 mg twice aday for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital

Full name of responsible person

Meghdad Sedaghat

Street address

Rasul_e Akram hospital, Mansuri Street, Sattarkhan Street

City

Tehran

Province

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1234567890

Phone

+98 21 6435 1000

Email

sedaghat@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Ziai

Street address

koodakyari street .velenjak

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1234567890

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mpd@sbmu.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meghdad Sedaghat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

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Person responsible for updating data

Contact

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

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

All data is shared after unidentifiable people

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use data to compare with other similar interventions

From where data/document is obtainable

Aylar fazlzadeh dr.aylar.fazlzadeh@gmail.com

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

email request

Comments