Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 improvment 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(NFLD), 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. physition 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

Inclution criterias; 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 IUl and ALT> 40 IUl Exclution criteria; positive viral hepatitis markers, positive Anti Mitocondrial Antibody(AMA) and Anti Nouclotide Antibody(ANA) , history of alcohol abuse, renal insufficiency, hypertention, pregnancy, cirrhosis, toxic hepetitis, 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 Plasebo 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.sbmu.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
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1234567890

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+98 21 6646 3443

Email
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

Street address
Rasul_e Akram hospital, Mansuri Street, Sattarkhan Street

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Person responsible for scientific inquiries

Contact

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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