Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Triple-blind clinical trial on the effect of a combination of garlic, silymarin and curcumin in comparison with placebo in the treatment of non-alcoholic fatty liver disease

Protocol summary

Study aim

Determination of the effect of a combination of garlic, silymarin and curcumin in comparison with placebo in the treatment of non-alcoholic fatty liver disease

Design

Pragmatic, community based, parallel group,Triple-blind , randomised controlled trial

Settings and conduct

Of the patients referred to the liver clinic of Emam Reza Hospital , 60 new case patients were diagnosed with nonalcoholic fatty liver disease . after that they give me the consent letter.These patients were randomly divided into two groups. They were treated with curcamine ,silymarin,garlic (380 mg -70 mg-200 mg /day) in the form of capsule or placebo for 3 months, plus a routine regimen with limited fat and carbohydrate.In the laboratory of the Emam Reza Hospital, blood samples were taken from brachialis vein of patients, for examination of the biochemical tests at the beginning and three months after starting the drug treatment . The level of biomarkers was then measured and compared ultrasonography.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Patients with abnormal LFT with sonographic patern of NAFLD-patients older than 18 years and younger than 70 years Exclusion criteria:diabetes mellitus-hypothyroidis-any drug users-sever cardiac disease-sever polmunary disease-past medical history of liver disease ,cancer,cirrhosis-pregnancy ,lactation-abnormal lab test:ANA,HBS Ag,HBC Ab,HCV Ab,ASMA,SI,Ferritin,TIBC,Anti TTG IgA , سرولوپلاسمین

Intervention groups

The intervention group received routine treatment of NAFLD with life style,nutritional recomendation with the administration of combination of garlic, silymarin and curcumin will be gave to patients for three months. Also, people underwent routine treatments of NAFLD with life style,nutritional recomendation

Main outcome variables

ALT-liver fat grading in Ultrasonography

General information

Reason for update

Acronym

GSC in NAFLD

IRCT registration information

IRCT registration number: **IRCT20190602043787N1**
Registration date: **2019-08-09, 1398/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-09, 1398/05/18**
Update count: **0**

Registration date

2019-08-09, 1398/05/18

Registrant information

Name

Zahra Ataee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

ataeez@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Triple-blind clinical trial on the effect of a combination of garlic, silymarin and curcumin in comparison with placebo in the treatment of non-alcoholic fatty liver disease

Public title
Triple-blind clinical trial on the effect of a combination of garlic, silymarin and curcumin in comparison with placebo in the treatment of non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
increased LFT plus sonographic evidenses of NAFLD age between 18-70 years
Exclusion criteria:
diabetes mellitus hypothyioidism any drug users sever cardiac disease or sever polmunary disease or past medical history of liver disease,cirrhosis,cancer pregnancy and lactation abnormal test include:ANA,HCV Ab,HBC Ab,HBS Ag,Anti TTG IgA,TIBC,Ferritin,SI,ASMA,seroloplasmin
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were devided to two groups by simple randomization through random number table that produced from PASS software. patients were randomized to receive drug (case) or matched-placebo(control) .
Blinding (investigator's opinion)
Triple blinded
Blinding description
patients were cured by healthcare providers with drug packages that coded and blinded for patients,analyzers,data collectors, outcome assessors by triple-blind trial .only main researcher get informed about contents of packages and coding.patients were followed by codes. For the control group, placebo was prescribed in the shape and color and size of the drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Emam Reza Hospital.Emam Reza Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2019-05-26, 1398/03/05
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.152

Health conditions studied

1

Description of health condition studied
fatty liver disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
1.decrease in serum level of ALT
Timepoint
at the baseline and 3 months after intervention
Method of measurement
autoanalyzer bt3000

Secondary outcomes

1

Description
decrease in ultrasonographic grading
Timepoint
at the baseline and 3 months after intervention
Method of measurement

ultrasonography

Intervention groups

1

Description
Intervention group:The intervention group received routine treatment with low intake of carbohydrate and fat with the administration of curcumin. garlic, silymarin in Soft gel , will be gave to patients for three months.curcumin has gave from curcumin plant and concentrated with HPLC,garlic and silymarin dried up then filled in capsules.
Category
Treatment - Drugs

2

Description
Control group: In this group, the placebo contains inert oil, with the same color as the drug that the drug manufacturer has produced, was given to patients with nonalcoholic fatty liver disease for a period of three months, in terms of shape and size, similar to the medicine.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
liver clinic in Emam Reza Hospital in Mashhad
Full name of responsible person
Dr Zahra Ataee
Street address
Emam Reza Ave.Emam Reza Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Quraish bilding of MUMS, daneshghah St, Mashhad, Iran Mashhad
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Ataee
Position
M.D , assistant professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Others
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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