# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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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Razavi Khorasan
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**Email**
zahraataee57@gmail.com

## 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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**Phone**
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zahraataee57@gmail.com
**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 scientific inquiries

**Contact**
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## Person responsible for updating data

**Contact**
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Hamid Reza Rahimi
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MD, PhD, assistant professor
**Latest degree**
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**Other areas of specialty/work**
Others
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Razavi Khorasan
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Rahimihr@mums.ac.ir

## 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