Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Investigation of the effect of piperine supplement on anthropometric indices, ultrasonographic findings, biochemical parameters and quality of life in patients with nonalcoholic fatty liver disease

Protocol summary

Study aim

The aim of this study is to evaluate of the effect of piperine supplement on on anthropometric indices, ultrasonographic findings, biochemical parameters and quality of life in patients with nonalcoholic fatty liver disease.

Design

64 patients with fatty liver after taking informed consent including 32 patients in case group and 32 patients in control group will be conducted parallel double blinded in the trial.

Settings and conduct

The trial will be performed in Tabriz Emam Reza hospital clinic by managing study and control groups. Piperine supplement(5mg) and placebo will be administered dayily for 12 weeks, while patients and physician are blind in the study. Lab tests and liver ultrasonography will be obtained and documented when referring patients to the clinic on schedules and at the end, by using the computer software the data will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Grade 2 and 3 non-alcoholic fatty liver ALT levels upper than 1.5 times the normal upper limit Exclusion criteria are: Chronic liver disease, diabetes, malignancy, hereditary diseases that affect the liver such as iron and copper storage disorder, untreated hypothyroidism, autoimmune disease, pregnancy, lactation, alcoholic fatty liver disease, consumption Alcohol, hepatitis Hypolipidemic and anti-inflammatory agents Bariatrics surgery in last year 43/5000Heavy diet to lose weight in the last 3 months Increase in fatty liver grade grade based on ultrasonographic findings during the study period Weight loss more than 10% during the study Discontent to continuation the study Not taking more than 10% of supplement

Intervention groups

In case group 5 mg of Piperine supplement daily for the three months will be prescribed and the control group will take placebo in same duration.

Main outcome variables

Fatty Liver Grading, Quality of Life, NAFLD Fibrosis Score, Fatty Liver Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180802040678N2**
Registration date: **2019-08-13, 1398/05/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-13, 1398/05/22**
Update count: **0**

Registration date

2019-08-13, 1398/05/22

Registrant information

Name

Masoud Nouri-Vaskeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3325 9778

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-11, 1398/05/20

Expected recruitment end date

2020-02-09, 1398/11/20

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

Scientific title
Investigation of the effect of piperine supplement on anthropometric indices, ultrasonographic findings, biochemical parameters and quality of life in patients with nonalcoholic fatty liver disease

Public title
Effect of piperine supplement in patients with non alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Grade 2 and 3 non-alcoholic fatty liver ALT levels upper than 1.5 times the normal upper limit
Exclusion criteria:
Chronic liver disease, diabetes, malignancy, hereditary diseases that affect the liver such as iron and copper storage disorder, untreated hypothyroidism, autoimmune disease, pregnancy, lactation, alcoholic fatty liver disease, consumption Alcohol, hepatitis Hypolipidemic and anti-inflammatory agents Bariatrics surgery in last year 43/5000Heavy diet to lose weight in the last 3 months Increase in fatty liver grade grade based on ultrasonographic findings during the study period Weight loss more than 10% during the study Discontent to continuation the study Not taking more than 10% of supplement
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data and Safety Monitoring Board

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomizing by computer software
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants-healthcare provider-data collectors
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166/15731
Approval date
2019-06-17, 1398/03/27
Ethics committee reference number
IR.TBZMED.REC.1398.291

Health conditions studied

1

Description of health condition studied
Non-Alcoholic Fatty Liver Disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Fattly Liver Grading
Timepoint
Before and after intervention
Method of measurement
Ultrasonography

2

Description
Quality of Life
Timepoint
Before and after intervention
Method of measurement
SF-36, CLDQ, and Disease Symptom Index 2.0 questionnaires

3

Description
Anthropometric indices
Timepoint

Before and after intervention

Method of measurement

Body weight and Body Mass Index

4

Description

Biochemical parameters

Timepoint

Before and after intervention

Method of measurement

Aspartate Aminotransferase, Alanine Aminotransferase, Alkaline Phosphatase, Bilirubin Total and Direct, Fasting Blood Suger, Triglyceride, LDL, HDL, VLDL, Hs-CRP, Total Cholesterol, Albumin, Count Blood Cells, HbA1C, HOMA-IR, Fecal Calprotectin

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of Piperine 5mg supplement daily for three months

Category

Treatment - Drugs

2

Description

Control group: Administration of placebo for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Leila Alizadeh

Street address

Golgasht Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Masoud Nouri-Vaskeh

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Leila Alizadeh

Position

Assistant Professor

Latest degree

Subspecialist

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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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Information about the study is available upon approval by the University's Ethics Committee.

When the data will become available and for how long

Starting access 6 months after publication of data

To whom data/document is available

Everybody

Under which criteria data/document could be used

Using is not authorized

From where data/document is obtainable

Applicants must send their request to the author

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

Sending the request via e-mail

Comments