Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Effect of Curcumin in treatment of Non-Alcoholic Fatty Liver Disease: A Randomized Double-blind Clinical Trial Including Placebo

Protocol summary

Summary

This study was designed as a double-blind randomized controlled trial on 100 Non-Alcoholic Fatty Liver patients. At start of study the patient of both groups evaluated for demographic variables, past medical history, age, height, BMI, duration of exercise per day, and diet. Adults (age > 18 y) with a diagnosis of Fatty Liver disease and a negative history of Hypersensitivity to Curcumin and Turmeric were recruited to the trial. Subjects with biliary diseases, Statin-treated Hyperlipidemia, pregnancy and lactation were excluded from the trial. Participants were randomized to Curcumin (1000 mg/day in two divided doses) and control groups and were treated for a period of 8 weeks. Response to treatment was evaluated using liver Doppler sonography at baseline and at the end of study. Determination of serum levels of hepatic transaminases, total and direct bilirubin, uric acid, lipids and glucose was also performed both at the start and end of the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122525641N2**
Registration date: **2016-01-16, 1394/10/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-16, 1394/10/26

Registrant information

Name

Parisa Kianpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2660 2854

Email address

pk.pioneer1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Baqiyatallah University of Medical Science

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-09-25, 1394/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Curcumin in treatment of Non-Alcoholic Fatty Liver Disease: A Randomized Double-blind Clinical Trial Including Placebo

Public title

The efficacy of Curcumin in treatment of Non-Alcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient has Fatty Liver; The history of allergic reaction to the drug combination is not relevant; Over 18 years old; The patient has informed consent to participate in the study; Exclusion criteria: The patient who stops the medication more than 1 week; The patient with the history of biliary disease; The patient with Fatty Liver, who also has Hyperlipidemia and receives statins; Patient with Fatty Liver, who also has another liver

disease; Pregnancy and lactation; The patient who expresses uncontrolled adverse effects by this drug; alcohol consumption and any addictive drugs.

Age
From **18 years** old to **139 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
It is a double-blind clinical trail in which neither patients nor analysis technician have no information about the kind of pharmacotherapy(drug or placebo) were received by patients. The Curcumin capsule was manufactured at Aburaihan Pharma Company. The Curcumin capsules are the extract of Turmeric, each capsule contains 500 mg Curcumin.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Science

Street address
Baqiyatallah University of Medical Science, Mollasadra St., Vanak

City
Tehran

Postal code

Approval date
2014-06-08, 1393/03/18

Ethics committee reference number
s/340/221

Health conditions studied

1

Description of health condition studied
Fatty Liver

ICD-10 code
k76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
The accumulation of liver fat

Timepoint
Before the intervention, 8 weeks later at the end of the intervention

Method of measurement
Color Doppler Ultrasonography

Secondary outcomes

1

Description
Portal vein diameter

Timepoint
Before the intervention, 8 weeks later at the end of the intervention

Method of measurement
Color Doppler Ultrasonography

2

Description
Hepatic blood flow velocity

Timepoint
Before the intervention, 8 weeks later at the end of the intervention

Method of measurement
Color Doppler Ultrasonography

3

Description
AST

Timepoint
Before the intervention, 8 weeks later at the end of the intervention

Method of measurement
Blood test

4

Description
ALT

Timepoint
Before the intervention, 8 weeks later at the end of the intervention

Method of measurement
Blood test

5

Description

HDL

Timepoint

Before the intervention, 8 weeks later at the end of the intervention

Method of measurement

Blood test

6

Description

Total Cholesetrol

Timepoint

Before the intervention, 8 weeks later at the end of the intervention

Method of measurement

Blood test

7

Description

LDL

Timepoint

Before the intervention, 8 weeks later at the end of the intervention

Method of measurement

Blood test

8

Description

TG

Timepoint

Before the intervention, 8 weeks later at the end of the intervention

Method of measurement

Blood test

9

Description

Uric Acid

Timepoint

Before the intervention, 8 weeks later at the end of the intervention

Method of measurement

Blood test

10

Description

FBS

Timepoint

Before the intervention, 8 weeks later at the end of the intervention

Method of measurement

Blood test

11

Description

HbA1C

Timepoint

Before the intervention,8 weeks later at the end of the intervention

Method of measurement

Blood test

Intervention groups

1

Description

Curcumin, 500 mg oral Capsule,2 times a day for 8 weeks

Category

Treatment - Drugs

2

Description

Placebo, 500mg oral capsule, twice a day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Mohtashami Reza(internist)

Street address

Baqiyatallah hospital, Mollasadra Ave., Vanak

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Baqiyatallah University of Medical Science

Full name of responsible person

Ahmadi Morteza(The Deputy Director of Research and Technology of Baqiyatallah University of Medical

Street address

Baqiyatallah University of Medical Science, South Sheikhbahaee St. , Mollasadra Ave., Vanak

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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

Vice chancellor for research of Baqiyatallah University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University of Pharmaceutical Science

Full name of responsible person

Kianpour Parisa

Position

Pharm.D student

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty