

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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 trial 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

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**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 Sheikhbahee St. , Mollasadra Ave., Vanak

**City**

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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*

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## Person responsible for general inquiries

### Contact

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## Person responsible for updating data

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## Person responsible for scientific inquiries

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**Full name of responsible person**  
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**Other areas of specialty/work**  
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**City**  
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## 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*