

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 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

**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 Sheikhbahee St. , Mollasadra Ave., Vanak

**City**

Tehran

**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*

**Postal code**  
**Phone**  
+98 21 8821 1524  
**Fax**  
**Email**  
yunespanahi@yahoo.com; pk.pioneer1@yahoo.com;  
pkp.pioneer1@yahoo.com  
**Web page address**

## 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**  
**Street address**  
Islamic Azad University of Pharmaceutical Science,  
Yakhchal St., Shariati Ave.  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 2264 0051  
**Fax**  
**Email**  
pk.pioneer1@yahoo.compkp.pioneer1@gmail.com  
**Web page address**

## Person responsible for updating data

### 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**  
**Street address**  
Islamic Azad University of Pharmaceutical Science,  
Yakhchal st., Shariati Ave.  
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Tehran  
**Postal code**  
**Phone**  
+98 21 2264 0051  
**Fax**  
**Email**  
pk.pioneer1@yahoo.compkp.pioneer1@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Baqiyatallah University of Medical Science  
**Full name of responsible person**  
Panahi Yunes  
**Position**  
Clinical Pharmacist  
**Other areas of specialty/work**  
**Street address**  
Baqiyatallah University of Medical Science, South  
Sheikhbahae St. , Mollasadra Ave., Vanak  
**City**  
Tehran

## 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*