

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Evaluation of influence of Curcumin on non-invasive liver marker`s in patients with nonalcoholic fatty liver disease

#### Protocol summary

##### Summary

According to studies on the effects of low health effects and side effects of Curcumin in treating non-alcoholic fatty liver disease in humans, the research done in this field in order to understand the mechanisms of effective dose estimates and impact it seems essential. A total of 60 patients will randomly divide into two groups of 30 and for two months to a 30-Member group of Curcumin, Curcumin will be prescribe to the amount of 80 mg 2 times a day and to the Placebo group, placebo will be prescribe to the group of 30. 2 months after applying the intervention, patients will be evaluate by and compare in laboratory and clinical criteria. Inclusion criteria: 1. having ALT and AST upper than highest normal level 2.the age of 15 to 60 Exclusion criteria: 1. Alcohol consumption 2. Get a positive serology of viral hepatitis Primary outcome measures are:ALT- AST; ALP; TG; Total Cholesterol; HDL; LDL; FGS; Serum Insulin; Total Bilirubin; Direct Bilirubin

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012031423N1**

Registration date: **2017-05-22, 1396/03/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-22, 1396/03/01

##### Registrant information

##### Name

Hosein Rajablou

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3588 2645

##### Email address

rajablouh901@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Financial sources are supplying from Vice chancellor for research, Mashhad University of Medical Sciences.

##### Expected recruitment start date

2017-02-19, 1395/12/01

##### Expected recruitment end date

2017-12-21, 1396/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of influence of Curcumin on non-invasive liver marker`s in patients with nonalcoholic fatty liver disease

##### Public title

The influence of Curcumin on Non-alcoholic fatty liver disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. having ALT and AST upper than highest normal level 2. have at least one of the following: A) Diabetes B) Hyperlipidemia C) Obesity 3. The age of 15 to 60 Exclusion criteria: 1. Alcohol consumption 2. Get a positive serology of viral hepatitis 3. ANA or AMA positive test, Alpha1 Antitrypsin, Low serum levels of Seroloplasin or high levels of antibodies of ASMA or LKM. 4. High ferritin 450 or Iron/TIBC> 45% 5. The patient

before the intervention or during the intervention, affected with acute or chronic disease that causes in LFT disorders. 6. The patient before the intervention or during the intervention is consuming medicine that potentially capable of Disrupting the LFT. 7. Pregnancy 8. Patients Younger than 15 or older than 60.

#### **Age**

From **15 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Sealed envelopes

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of mashhad university of medical sciences

##### **Street address**

University street, Ghoreishi building, Vice Chancellor of Research Mashhad University of Medical Sciences

##### **City**

Mashhad

##### **Postal code**

#### **Approval date**

2016-12-13, 1395/09/23

#### **Ethics committee reference number**

IR.MUMS.fm.REC.1394.690

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Nonalcoholic fatty liver disease

#### **ICD-10 code**

K76.0

#### **ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

## **Primary outcomes**

### 1

#### **Description**

BMI

#### **Timepoint**

Before and two months after intervention

#### **Method of measurement**

Measuring the weight by Scale and height by Metre

### 2

#### **Description**

ALT

#### **Timepoint**

Before and two months after intervention

#### **Method of measurement**

Serology

### 3

#### **Description**

AST

#### **Timepoint**

Before and two months after intervention

#### **Method of measurement**

Serology

### 4

#### **Description**

ALP

#### **Timepoint**

Before and two months after intervention

#### **Method of measurement**

Serology

### 5

#### **Description**

TG

#### **Timepoint**

Before and two months after intervention

#### **Method of measurement**

Serology

### 6

#### **Description**

Total Cholesterol

#### **Timepoint**

Before and two months after intervention

#### **Method of measurement**

Serology

### 7

#### **Description**

HDL

#### **Timepoint**

Before and two months after intervention  
**Method of measurement**  
Serology

## 8

**Description**  
FBS

**Timepoint**  
Before and two months after intervention

**Method of measurement**  
Serology

## 9

**Description**  
Serum Insulin

**Timepoint**  
Before and two months after intervention

**Method of measurement**  
Serology

## 10

**Description**  
LDL

**Timepoint**  
Before and two months after intervention

**Method of measurement**  
Serology

## 11

**Description**  
Total Bilirubin

**Timepoint**  
Before and two months after intervention

**Method of measurement**  
Serology

## 12

**Description**  
Direct Bilirubin

**Timepoint**  
Before and two months after intervention

**Method of measurement**  
Serology

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

**Description**  
Control group: Patients in groups of 30 for a period of two months Placebo 2 times a day will be prescribed

**Category**  
Placebo

### 2

**Description**  
Intervention group: Patients in groups of 30 for a period of two months curcumin(Sinacurcumin; nanomicelles) to 80 mg 2 times a day will be prescribed

**Category**  
Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ghaem hospital subspecialty clinics

##### **Full name of responsible person**

DR Beheshti Namdar, Ali(Gastroenterologist; Assistant Professor)

##### **Street address**

Ghaem hospital; Ahmad abad

##### **City**

Mashhad

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for research of Mashhad University of Medical Sciences

##### **Full name of responsible person**

DR tafaghodi, Mohsen

##### **Street address**

University street, Ghoreishi building, Vice Chancellor of Research Mashhad University of Medical Sciences

##### **City**

Mashhad

##### **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 Mashhad University of Medical Sciences

##### **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**

Mashhad University of Medical Sciences

**Full name of responsible person**

DR Beheshti Namdar, Ali

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Ghaem hospital; Ahmad abad

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beheshtia@mums.ac.ir

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Mashhad University of medical Sciences

**Full name of responsible person**

DR Beheshti Namdar, Ali

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Ghaem Hospital; Ahmad abad

**City**

Mashhad

**Postal code****Phone**

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**Fax****Email**

beheshtia@mums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Uedical Sciences

**Full name of responsible person**

Rajablou, Hosein

**Position**

Medical Intern

**Other areas of specialty/work****Street address**

Shahid bahonar Blv; Vakil abad

**City**

Mashhad

**Postal code****Phone**

00

**Fax****Email**

rajabloo.hosein@gmail.com

**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*