Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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

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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 Cholestrol

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
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Person responsible for scientific inquiries

Contact
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Mashhad Universty of medical Sciences
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DR Beheshti Namdar, Ali
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Uedical Sciences
Full name of responsible person
Rajablou, Hosein
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Medical Intern
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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