

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Evaluation of curcuma (turmeric) efficacy on biochemical and liver sonography criteria in non-alcoholic fatty liver patients

Protocol summary

Study aim

The aim of this study is to evaluate Curcuma (turmeric) efficacy on biochemical and liver sonography criteria in non-alcoholic fatty liver patients.

Design

The study is done randomly, single blind and use of placebo as a control group.

Settings and conduct

At the beginning patients are evaluated for metabolic syndrome criteria such as FBS, lipid profile, systolic and diastolic blood pressure, circumflex and BMI. AST ALT hcRP and liver sonography is also done to score and grading the fatty liver. the patients in first group treat by 20mg Curcuma(1 tablet daily) for 8 weeks and the second group treat by 1 tablet of placebo Curcuma daily for 8 weeks. At the end of 8th week laboratory tests will be rechecked and liver sonography is done again. the results in both groups will compare and analyse.

Participants/Inclusion and exclusion criteria

The entrance criteria included as sign up the testimonial, age 30-65 year, no smoking or drug abuse, no diabetes, no alcoholic, negative screening for viral hepatitis, infection disease, cirrhosis. No history of using hepatotoxic drugs and not being pregnant or lactating. the one who has these problems exits from study.

Intervention groups

100 patients who diagnosed as NAFLT with examination, liver function tests, sonography, history taking and high AST ALT were chosen. Patients divide in 2 equal groups. The first group named as Curcuma group, using 1 Curcuma tablets daily and the second group using 1 placebo tablets daily is named control group.

Main outcome variables

Reduction of Liver Function Tests in Patients with Non-Alcoholic Fatty Liver; Improvement of sonographs results in patients with nonalcoholic fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170722035222N2**

Registration date: **2018-04-18, 1397/01/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-18, 1397/01/29**

Update count: **0**

Registration date

2018-04-18, 1397/01/29

Registrant information

Name

Bahram Pakzad

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of curcuma (turmeric) efficacy on biochemical and liver sonography criteria in non-alcoholic fatty liver patients

Public title

evaluation of Curcuma tablet efficacy in nonalcoholic fatty liver patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who diagnosed as NAFLT with examination, liver function tests, sonography, history taking and high AST ALT age 30-65 year sign up the testimonial

Exclusion criteria:

smoking or drug abuse diabetes alcoholic viral hepatitis infection disease cirrhosis history of using hepatotoxic drugs such as methotrexate, amiodarone, valproic acid, anabolic steroid, estrogen, glucocorticoids and ... being pregnant or lactating hypotension

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 100 patients were randomly selected from NAFLD. Then, patients were randomly assigned to two equal groups of 50 patients with curcumin and control. The curcumin group received a single dose of 20 mg of curcuma per day for 8 weeks and the control group received the same amount of placebo for eight weeks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, after signing up the testimonial, as a research-therapeutic drug, Curcuma was given to the first group and placebo given to the second group. Patients are not informed about whether they are taking placebo or Curcuma.

Placebo

Used

Assignment

Parallel

Other design features

the results in both groups compare and analyse with SPSS software. using Paired T test, independent T test and X2 for intra group and inter groups comparing.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St, Isfahan university of medical sciences

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2017-09-18, 1396/06/27

Ethics committee reference number

IR.mui.REC.3.621

Health conditions studied

1

Description of health condition studied

nonalcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

AST

Timepoint

Before intervention and 8 weeks after drug therapy

Method of measurement

Serum per liter in biochemical tests

2

Description

ALT

Timepoint

Before intervention and 8 weeks after drug therapy

Method of measurement

Serum per liter in biochemical tests

3

Description

liver sonography

Timepoint

Before intervention and 8 weeks after drug therapy

Method of measurement

Assessing the grade of fatty liver based on the accumulation of fatty vacuoles in liver cells

Secondary outcomes

1

Description

BMI

Timepoint

Before intervention and 8 weeks after drug therapy

Method of measurement

In kilograms per meter using the BMA calculation formula

2

Description

FBS

Timepoint

Before intervention and 8 weeks after drug therapy

Method of measurement

In mg per deciliter in biochemical tests

3

Description

Weight

Timepoint

Before intervention and 8 weeks after drug therapy

Method of measurement

In kilograms using digital scales

Intervention groups

1

Description

Intervention group: Patients in this group are treated with one 20 mg Curcuma tablet (Dina Company) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group receive one placebo tablet per day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan university of medical sciences Alzahra Medical Center

Full name of responsible person

Dr Arash Hedayat resident of internal medicine

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Isfahan, Shahid Keshari Highway Sofhe boulevard, Al-Zahra Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Arash Hedayat

Position

resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available