Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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 sonogrsphy 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

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Name of organization / entity
Isfahan university of medical dciences
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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 sofware. 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
Isfehan

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 boulvared, Al-Zahra Medical Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Dr Arash Hedayat
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resident of 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