Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of effect of Curcumin on the serum levels of 12-inflammatory cytokines and highly sensitive C-reactive protein level in the patients with Non-alcoholic fatty liver disease (A double-blind, randomized, placebo-controlled trial)

Protocol summary

Study aim

The aim of this study is evaluation of effect of Curcumin on non- alcoholic fatty liver disease treatment and the serum levels of inflammatory cytokines and highly sensitive C-reactive protein (hsCRP) in the patients with non- alcoholic fatty liver (NAFLD).

Design

This study is an 2-months, concealed, randomized, double-blind, placebo-controlled, parallel-group conduct in Neyshabur city in the north east of Iran. The allocation ratio is 1:1 for three groups. The study groups contains two intervention groups of Curcumin with dose of 250 mg/day and 500 mg/day and Placebo group whose receives lactose with dose of 250 mg/day. Sample size of each groups is 40 patients.

Settings and conduct

In order to the random allocation sequence, the entire randomization process is concealed. For this purpose, the drugs are already put in envelopes labeled a serial number from 1 to 120. No one know the nature of the envelopes except the coordinator of the trial.

Participants/Inclusion and exclusion criteria

Referred patients of the 22 Bahman Hospital (Neyshabur, Iran) is recruited. The inclusion criteria is as follow: age between 18–65 years and the diagnosis of fatty liver using ultrasound and the exclusion criteria were women with pregnancy/lactation, taking anti-inflammatory drugs such as Curtin and liver enzyme enhancement drugs, acute or chronic liver disorders such as viral (hepatitis B and C) and autoimmune hepatitis, hyper/hypothyroidism, alpha-1 antitrypsin deficiency, celiac disease and cancer.

Intervention groups

Intervention groups consists of two groups. One group patients receives capsules of phospholipidated Curcumin (Meriva curcumin phytosome) with a dose of 250 mg/day after dinner and other group receives Curcumin C3 complexTM (500 mg) plus BioperineTM.

Main outcome variables

NAFLD grade, liver function tests including AST, ALT and ALP, MCP-1, IL-10, IL-6, TNF- alpha and hsCRP

General information

Reason for update

Errors and mistakes during submissions of the protocol by the user and minor and possible protocol changes during project execution

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052322381N1**
Registration date: **2016-09-17, 1395/06/27**
Registration timing: **prospective**

Last update: **2019-10-22, 1398/07/30**
Update count: **1**

Registration date

2016-09-17, 1395/06/27

Registrant information

Name
Azam Rezaei Farimani
Name of organization / entity
Neyshabur University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 4334 4011
Email address
rezaia1@nums.ac.ir

Recruitment status

Recruitment complete

Funding source

Neyshabur University of Medical Sciences (research

grants)

Expected recruitment start date
2016-08-22, 1395/06/01
Expected recruitment end date
2017-03-21, 1396/01/01
Actual recruitment start date
2017-01-23, 1395/11/04
Actual recruitment end date
2017-08-30, 1396/06/08
Trial completion date
2017-11-07, 1396/08/16

Scientific title
Evaluation of effect of Curcumin on the serum levels of 12-inflammatory cytokines and highly sensitive C-reactive protein level in the patients with Non-alcoholic fatty liver disease (A double-blind, randomized, placebo-controlled trial)

Public title
Evaluation of effect of Curcumin on the serum levels of 12-inflammatory cytokines & highly sensitive C-reactive protein
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18–65 years The diagnosis of fatty liver using ultrasound
Exclusion criteria:
Women with pregnancy/lactation Alcoholic liver disease Taking anti-inflammatory drugs such as Curtin Acute or chronic liver disorders such as viral (hepatitis B and C) and autoimmune hepatitis Metabolic liver disorders including hemochromatosis and Wilson's disease, Budd–Chiari syndrome Having other medical disorders such as cardiovascular diseases and cancer Taking liver enzyme enhancement drugs Have severe heart and lung disease Hypothyroidism and hyperthyroidism Alpha-1 antitrypsin deficiency Celiac disease
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **43**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Two letters were prepared and written on two sheets "A" for "curcumin" and "B" for "control." AABB, ABAB, ABBA, BBAA, BABA, BAAB, all quad blocks were possible. Then the number was selected randomly via a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
To ensuring that implementation of the random allocation sequence occurs without the knowledge of which patient will receive which treatment, the entire randomization process was concealed. For this purpose, the drugs were already put in envelopes labeled a serial number from 1 to 80. No one knew the nature of the envelopes except the coordinator of the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Neyshabur University Of Medical Sciences
Street address
Razi St, Shahid Jafari St, Imam Khomeini Square, Neyshabur, Iran
City
Neyshabur
Province
Razavi Khorasan
Postal code
93186-14139
Approval date
2016-02-20, 1394/12/01
Ethics committee reference number
IR.NUMS.REC.1394.18

Health conditions studied

1

Description of health condition studied
NAFLD
ICD-10 code
K75.8
ICD-10 code description
nonalcoholic steatohepatitis

Primary outcomes

1

Description
NAFLD grade
Timepoint

Before intervention and two months after intervention

Method of measurement

Sonography

2

Description

Tumor necrosis factor alpha (TNF-α)

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

3

Description

High-sensitivity C-reactive Protein (hs-CRP)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto-analyzer BT-2000

4

Description

Interleukin 6 (IL-6)

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

5

Description

Interleukin 10 (IL-10)

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

6

Description

Monocyte Chemoattractant Protein-1 (MCP-1)

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Aspartate Aminotransferase (AST)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

2

Description

Alanine Aminotransferase (ALT)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

3

Description

Alkaline Phosphatase (ALP)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

4

Description

Fasting blood sugar (FBS)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

5

Description

Triglyceride (TG)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

6

Description

Total cholesterol (TC)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

7

Description

High-density lipoprotein cholesterol (HDL-C)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

8

Description

Low-density lipoprotein cholesterol (HDL-C)

Timepoint

Before intervention and two months after intervention

Method of measurement

Auto Analyzer BT-2000

Intervention groups

1

Description
Curcumin Phytosome (Meriva) with dose 250 mg/day (phospholipidated curcumin, 250 mg equivalent to 50 mg curcumin)
Category
Treatment - Drugs

2

Description
Curcumin C3 complexTM (500 mg) plus BioperineTM (5 mg, patented extract obtained from black pepper fruits (Piper nigrum) standardized minimum to 95% Piperine.
Category
Treatment - Drugs

3

Description
Control group or Placebo consumes capsules lactose with similar shape and size of intervention groups and a dose of 250 mg/day. Drug consumption is as oral during a 2-month period.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
22 Bahman Hospital
Full name of responsible person
Dr. Mahdi Pakdaman
Street address
22 Bahman hospital, Emam Khomeini street, Neyshabur, Iran.
City
Neyshabur
Province
Razavi Khorasan
Postal code
93186-14139
Phone
+98 51 4262 7522
Email
info@nums.ac.ir
Web page address
https://www.nums.ac.ir/2015-04-19-07-19-48/2015-04-27-15-00-08.html

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Neyshabour University of Medical Sciences
Full name of responsible person
Dr. Abasalt Borji
Street address
Office of Research Affairs, Razi St, Shahid Jafari St, Imam Khomeini Square, Neyshabur, Iran
City
Neyshabur
Province
Razavi Khorasan
Postal code
93186-14139
Phone
+98 51 4262 7522
Email
info@nums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Neyshabour 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
Neyshabour University of Medical Sciences
Full name of responsible person
Dr Seyed Reza Mirhafez
Position
Asistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Cardiology
Street address
Office of Research Affairs, Razi St, Shahid Jafari St, Imam Khomeini Square, Neyshabur, Iran
City
Neyshabur
Province
Razavi Khorasan
Postal code
93186-14139
Phone
+98 51 4334 4011
Fax
Email
mirhafezr@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Neyshabour University of Medical Sciences

Full name of responsible person
Dr.Seyed Reza Mirhafz

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Cardiology

Street address
Office of Research Affairs, Razi St, Shahid Jafari St, Imam Khomeini Square, Neyshabur, Iran

City
Neyshabur

Province
Razavi Khorasan

Postal code
93186-14139

Phone
+98 51 4334 4011

Fax

Email
Mirhafezr@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Neyshabour University of Medical Sciences

Full name of responsible person
Dr. Seyed Reza Mirhafez

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Cardiology

Street address
IOffice of Research Affairs, Razi St, Shahid Jafari St, Imam Khomeini Square, Neyshabur, Iran

City
Neyshabur

Province
Razavi Khorasan

Postal code
93186-14139

Phone
+98 51 4262 7522

Fax

Email
mirhafezr@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
If the request is made by a researcher, the data will be shared according to the relevant criteria.

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