Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effects of Nanocurcumin supplementation on fibrosis، steatosis، Inflammatory and metabolic status of liver fibrosis patients with non-alcoholic fatty liver origin

Protocol summary

Study aim

The effects of nanocurcumin supplementation on fibrosis، steatosis، Inflammatory and metabolic status of liver fibrosis patients with non-alcoholic fatty liver origin

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. Blocked randomization will be used for randomization.

Settings and conduct

50 patients will be selected among referring to Gastroenterology and endocrinology Clinic. At the beginning and end of the study (end of week 16), 14 ml of fasting blood samples will be taken. In this way, the appearance of the capsules will be the same and their packaging will be the same. Coding (A and B) will be done by someone outside the study. The given codes will be provided to the researchers after the statistical analysis of the data and when writing the article. At the beginning of the study and at the end of the fourth month, the liver fibrosis and steatosis will be determined by fibroscan, anthropometric factors including weight, height, waist circumference, body composition,and inflammatory, metabolic factors and blood pressure will be measured for all patients. Also, 3-day food recall questionnaire, physical activity questionnaire, and demographic information will be completed from the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 30 and 70 years of age with liver fibrosis F≥2 exclusion criteria: Alcohol addiction Suffering from other chronic and acute liver disorders Pregnancy or breastfeeding current Lung and kidney disease and history of cancer Drug abuse Treatment with anti-inflammatory, hepatotoxic, corticosteroids and hormones medications Use of weight loss medication or diets current warfarin medications

Intervention groups

1 capsule of 40 mg of nanocurcumin or 1 capsule of identical-looking placebo two times daily.

Main outcome variables

liver fibrosis and steatosis

General information

Reason for update

The aforementioned clinical trial was registered in the april of 2023 and patient recruitment began thereafter. Patient recruitment for this clinical trial is still ongoing in August 2024. Unfortunately, due to an unintentional error during registration with the IRCT, the expected completion date was mistakenly entered The same as the start date. Consequently, the aforementioned clinical trial was erroneously registered as a retrospective and terminated study, even though it is still ongoing.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051098N2**
Registration date: **2023-04-20, 1402/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-13, 1403/05/23**
Update count: **1**

Registration date

2023-04-20, 1402/01/31

Registrant information

Name
Sayyed Saeid Khayyatzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3820 9100
Email address
khayyatzadeh@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-20, 1402/01/31
Expected recruitment end date
2024-12-20, 1403/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effects of Nanocurcumin supplementation on fibrosis، steatosis، Inflammatory and metabolic status of liver fibrosis patients with non-alcoholic fatty liver origin

Public title
The effect of Nanocurcumin on liver fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients between 30 and 70 years of age with liver fibrosis F≥2 referring to the liver and digestive consultation and treatment clinic
Exclusion criteria:
History of alcohol intake or current intake of alcohol evidence of other forms of chronic and acute liver diseases (such as viral hepatitis B, C etc), biliary disease, known autoimmune hepatitis and hereditary disorders affecting the liver (storage disease of iron, copper etc) current pregnancy or breastfeeding Use of hepatotoxic medication current Lung and kidney disease Drug abuse, history of cancer Treatment with anti-inflammatory, corticosteroids and hormones medication Use of weight loss medication or diets Intolerance or allergy to the supplement Unwillingness to participate in the study New diet Changes in the patient's medications Patients with current warfarin medications
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
50 patients with liver fibrosis, who have inclusion criteria and do not have exclusion criteria, based on a pre-designed random list (the list will be designed through the website https://www.sealedenvelope.com/simple-randomiser/v1/lists)) will be randomly assigned to two groups to receive curcumin or placebo. Each drug package is assigned a code, the codes will be A and B. To reduce the bias in placing people in the treatment or placebo groups, patients will be randomly assigned to one of the two nanocurcumin or placebo groups using the blocked randomization method (the size of the blocks is 4).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blinding will be done in the type of supplement or placebo for researchers and patients. In this way, the appearance of the capsules will be the same and their packaging will be the same. Coding (codes will be A and B) will be done by someone outside the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Yazd - Alam Square - Shahid Sadougi University of Medical Sciences
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۶۰
Approval date
2023-01-29, 1401/11/09
Ethics committee reference number
IR.SSU.SPH.REC.1401.157

Health conditions studied

1

Description of health condition studied
Liver fibrosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
liver fibrosis
Timepoint
Before and 16 weekes after the intervention
Method of measurement
Determining the amount of liver tissue fibrosis by using Elastography (2D Shear Wave Elastography- SWE)

2

Description
liver steatosis
Timepoint
Before and 16 weekes after the intervention
Method of measurement
Determining the amount of liver tissue steatosis by using Elastography (2D Shear Wave Elastography- SWE)

Secondary outcomes

1

Description
Liver function tests (LDH ،ALT،AST،Albumin ،GGT ،ALP،Bilirubin Total and Bilirubin Direct)
Timepoint
Baseline and 16 weeks
Method of measurement
lab kit

2

Description
Lipid profile (HDL-c, LDL-c, TG, TC)
Timepoint
Baseline and 16 weeks
Method of measurement
lab kit

3

Description
Fasting glucose, serum insulin
Timepoint
Baseline and 16 weeks
Method of measurement
lab kit

4

Description
Inflammatory factors Hs-CRP and ESR
Timepoint
Baseline and 16 weeks
Method of measurement
lab kit

5

Description
Anthropometric indicators (weight)
Timepoint
Baseline and 16 weeks
Method of measurement
Weight of a person with light clothes and without shoes (Kg)

6

Description
Anthropometric indicators (waist circumference)
Timepoint
Baseline and 16 weeks
Method of measurement
Waist size in the distance between the hip bone and the last rib (cm)

7

Description
Anthropometric indices (body mass index)
Timepoint
Baseline and 16 weeks
Method of measurement
The ratio of weight (in kilograms) to the square of height (in meters)

8

Description
Anthropometric indicators (fat mass and fat-free mass)
Timepoint
Baseline and 16 weeks
Method of measurement
Using the body composition device

9

Description
blood pressure
Timepoint
Baseline and 16 weeks
Method of measurement
Measurement of systolic and diastolic blood pressure (mm Hg)

Intervention groups

1

Description
Intervention group:Nanocurcumin 40 mg Exir Nano Sina (twice a day),The patients will be received 1 capsule of 40 mg of nano curcumin two times daily for 4 months.
Category
Treatment - Drugs

2

Description

Control group: Placebo (twice a day), The patients will be received 1 capsule of an identical-looking placebo two times daily for 4 months (Appearance similarity of both supplement and placebo in terms of shape and color).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal and Liver Diseases Research Center

Full name of responsible person

Sayyed Saeid Khayyatzadeh

Street address

Tehran, Kargar North Street, Jalal Al Ahmad three way, Dr. Shariati Educational Research and Treatment Center.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

Street address

Yazd - Imam Hossein Square - Student Blvd - Imam Reza Research Educational Complex - Vice President of Research and Technology of Shahid Sadougi University of Medical Sciences, Yazd

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Province

Yazd

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Phone

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dvc.research@ssu.ac.ir

Grant name

Dr. Amin Salehi Abargouei/ Vice Chancellor of Research and Technology, Shahid Sadoughi University of Medical Sciences, Yazd

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Hadis Gerami

Position

PhD student in nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Yazd - Alam Square - Shahid Sadougi University of Medical Sciences - Faculty of Health - Department of Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sayyed Saeid Khayyatzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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Yazd University of Medical Sciences

Full name of responsible person

Hadis Gerami

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

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Phone

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Email

geramihadis@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Not applicable

Title and more details about the data/document

Data collected for the primary and secondary outcomes will be shared.

When the data will become available and for how long

Access starting 6 months after publication

To whom data/document is available

he data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by for conducting Meta-analysis.

From where data/document is obtainable

To access the required data, the researchers can contact Dr. Sayyed Saeid Khayyatzadeh: email address: khayyatzadeh@yahoo.com

What processes are involved for a request to access data/document

The request will be assessed by the our group, and if all of us agree to the request, the requested data will be emailed.

Comments