Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Evaluating Cinnamon Effects on Clinical, Serologic and Sonographic Characteristics of Non-Alcoholic Fatty Liver Disease patients

Protocol summary

Summary

This prospective randomized double blinded placebo controlled trail aims to seek whether daily intake of 1500 mg oral Cinnamon exceeds placebo in improving clinical, serologic and sonographic characteristics of NAFLD patients during a 3 month treatment program. This parallel designed trail will be conducted in gastroenterology outpatient clinic affiliated to Ahvaz University of Medical Sciences starting from June 2015 to October 2015. Participants are randomly allocated to one treatment arm with 750 mg cinnamon capsules twice daily for three months, and one control arm receiving sham capsules of identical shape and size with the same duration. The primary outcome measures are changes in clinical, serologic and radiologic characteristics of NAFLD patients involved in the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922977N1**
Registration date: **2015-07-20, 1394/04/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-20, 1394/04/29

Registrant information

Name

Eskandar Hajiani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1292 1839

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hajiani-e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Development Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-07-15, 1394/04/24

Expected recruitment end date

2015-10-15, 1394/07/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating Cinnamon Effects on Clinical, Serologic and Sonographic Characteristics of Non-Alcoholic Fatty Liver Disease patients

Public title

Evaluating Cinnamon Effects on Clinical, Serologic and Sonographic Characteristics of Non-Alcoholic Fatty Liver Disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria (consenting NAFLD patients 18-65 years old; evidence of fatty liver in ultrasonography with a score of 2 or more or alanine aminotransferase (ALT) levels up to 60 U/L;) and exclusion criteria (daily alcohol consumption above 20 g in women and 30 g in men; incidence of other acute or chronic liver diseases (hepatitis B, C, etc); cirrhosis; biliary disease; known autoimmune disease; malignancy and/or inherited disorders that affect liver status (an iron storage disease,

Wilson disease, etc); pregnancy and lactation; metformin consumption; incidence of hyperlipidemia or hypertension requiring medication; previous supplementation of vitamin E; usage of hepatotoxic drugs over the past 6 months prior to the trial; developing hypersensitivity to cinnamon or occurring any adverse effects; acquiring viral/autoimmune/metabolic hepatic disorders during the study; alcohol intake; withdrawing treatment or being lost to follow up clinical and para-clinical examinations)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Ethics Committee, It & Research Assistance Center, University complex, Golestan Hwy

City
Ahvaz

Postal code

Approval date
2015-04-29, 1394/02/09

Ethics committee reference number
AJUMS.REC.1394.45

Health conditions studied

1

Description of health condition studied
Non-Alcoholic Fatty Liver Disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Fatty liver score in ultrasound

Timepoint
Before intervention and after three months of intervention

Method of measurement
Ultrasound evaluations of abdomen

2

Description
Fasting Blood Sugar (FBS)

Timepoint
Before intervention and after three months of intervention

Method of measurement
colorimetric enzymatic method

3

Description
HbA1C

Timepoint
Before intervention and after three months of intervention

Method of measurement
measured by affinity chromatographic method

4

Description
Triglycerides, Total Cholesterol, Low-density Lipoprotein (LDL), and High-density Lipoprotein (HDL)

Timepoint
Before intervention and after three months of intervention

Method of measurement
Colorimetric Enzymatic Method

5

Description
Serum ALT and AST Concentration

Timepoint
Before intervention and after three months of intervention

Method of measurement
UV Test

6

Description
Weight (kg)

Timepoint

Before intervention and after three months of intervention

Method of measurement

Digital scale with minimal clothing and no shoes

7

Description

Body Mass Index (BMI)

Timepoint

Before intervention and after three months of intervention

Method of measurement

Weight (kilograms) divided by the square of height (meters)

8

Description

Waist Circumference

Timepoint

Before intervention and after three months of intervention

Method of measurement

non-stretchable tape without any pressure (cm)

Secondary outcomes

empty

Intervention groups

1

Description

In the treatment group (Cinnamon group) all patients will receive 750 mg cinnamon capsules twice daily for 12 weeks starting after initial assessments

Category

Treatment - Drugs

2

Description

In the control group, all patients will receive 750 mg placebo capsules (wheat flour) of identical shape and color twice daily for 12 weeks starting after initial assessments

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Outpatient Clinic affiliated to Ahvaz University of Medical Sciences

Full name of responsible person

Eskandar Hajiani

Street address

Department of gasteroenterology, Imam Khomeini Hospital, Azadegan Ave Ahvaz Khuestan Iran, Islamic Republic Of

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research Development Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Nader Saki, Deputy of research development

Street address

IT & research center, University complex

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research Development Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Eskandar Hajiani

Position

Associate Professor of Gastroenterology

Other areas of specialty/work

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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