

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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)

###### Phone

+98 61 1292 1839

##### Email address

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 gastroenterology, 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**

**Street address**

Department of gastroenterology, Imam Khomeini Hospital, Azadegan Ave

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Eskandar Hajiani

**Position**

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**Other areas of specialty/work****Street address**

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## Person responsible for updating data

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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*