

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effects of cinnamon on lipid profile, liver enzymes, insulin resistance and hs-CRP inflammatory factor, in patients with Nonalcoholic Steatohepatitis

#### Protocol summary

##### Summary

In this study, 50 patients with Nonalcoholic Steatohepatitis (NASH) who referred to Gastrointestinal (GI) clinic with steatosis grade 1 or more will be randomly assigned to receive either 6 gr cinnamon or placebos for 3 months; both groups will be advised to adherence our diet and exercise program too. At the first and the end of the intervention, lipid profiles, liver enzymes and hs-CRP will be assessed and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207114010N9**  
Registration date: **2013-01-11, 1391/10/22**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-01-11, 1391/10/22

##### Registrant information

##### Name

Azita Hekmatdoost

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
National Institute of Nutrition Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2293 0824

##### Email address

hekmat@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

National Nutrition and Food Technology Research  
Institute (NNFTRI)

##### Expected recruitment start date

2012-09-05, 1391/06/15

##### Expected recruitment end date

2012-12-20, 1391/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of cinnamon on lipid profile, liver enzymes, insulin resistance and hs-CRP inflammatory factor, in patients with Nonalcoholic Steatohepatitis

##### Public title

The effects of cinnamon on lipid profile, liver enzymes, insulin resistance and hs-CRP inflammatory factor, in patients with Nonalcoholic Steatohepatitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age, 18 - 65 years old; Abnormal serum transferase (ALT & AST more than 1/5 fold of normal range); Sonographic findings compatible with hepatic steatosis (degree 1 or more); NASH was diagnosed during previous 6 months; no history of alcohol consumption; absence of Pregnancy, lactation, and Professional athletic; absence of other hepatobiliary disorders, autoimmune disease, malignancies, and endocrine disorders; absence of taking any medications in last 3 months. Exclusion criteria: Evidence of any allergic reaction to cinnamon; pregnancy; disliking to

continue study with any reason.

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

National Nutrition and Food Technology Research  
Institute (NNFTRI)

**Street address**

#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak  
Gharb

**City**

tehran

**Postal code**

1981619573

**Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

047489

**2****Ethics committee****Name of ethics committee**

National Nutrition and Food Technology Research  
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**City**

Tehran

**Postal code**

1981619573

**Approval date**

2012-11-17, 1391/08/27

**Ethics committee reference number**

047489

**Health conditions studied****1****Description of health condition studied**

Nonalcoholic steatohepatitis (NASH)

**ICD-10 code**

K75.8

**ICD-10 code description**

Nonalcoholic steatohepatitis (NASH)

**Primary outcomes****1****Description**

hs-CRP

**Timepoint**

at the beginning and at the last

**Method of measurement**

ELISA

**2****Description**

cholesterol, TG, LDL-c, HDL-c

**Timepoint**

at the beginning and at the last

**Method of measurement**

Biochemistry

**3****Description**

ALT, AST, GGT

**Timepoint**

at the beginning and at the last

**Method of measurement**

Biochemistry

**4****Description**

FBS

**Timepoint**

at the beginning and at the last

**Method of measurement**

Biochemistry

**5****Description**

insulin

**Timepoint**

at the beginning and at the last

**Method of measurement**

elaisa

## 6

### **Description**

insulin resistance

### **Timepoint**

at the beginning and at the last

### **Method of measurement**

formula

## **Secondary outcomes**

### 1

### **Description**

waist circumference

### **Timepoint**

at the beginning and at the last

### **Method of measurement**

non stretch meter

### 2

### **Description**

weight and BMI

### **Timepoint**

at the beginning and at the last

### **Method of measurement**

Weight will be measured by Secca scale , BMI by formula

## **Intervention groups**

### 1

### **Description**

Intervention: 4cinnamon capsules daily for 3 months

### **Category**

Treatment - Drugs

### 2

### **Description**

Control: 4 placebo capsule (wheat flour) daily for 3 months

### **Category**

Placebo

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

Gastrointestinal and liver disease clinic

#### **Full name of responsible person**

Azita Hekmatdoost

#### **Street address**

#### **City**

Tehran

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

National Nutrition and Food Technology Research Institute (NNFTRI)

#### **Full name of responsible person**

Dr Majid Hajifaraji

#### **Street address**

#41, West Arghavan, Farahzadi BLV, Shahrak Gharb

#### **City**

Tehran

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

National Nutrition and Food Technology Research Institute (NNFTRI)

### **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**

National Nutrition and Food Technology Research Institute (NNFTRI)

#### **Full name of responsible person**

Dr Azita Hekmatdoost

#### **Position**

MD, PhD/ Assistant Prof

#### **Other areas of specialty/work**

#### **Street address**

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#### **Web page address**

## **Person responsible for scientific inquiries**

### **Contact**

#### **Name of organization / entity**

National Nutrition and Food Technology Research Institute (NNFTRI)

**Full name of responsible person**

Dr Azita Hekmatdoost

**Position**

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**Web page address****Person responsible for updating data****Contact****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*