Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 Institute (NNFTRI

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

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
cholestrol, 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
#7, West arghavan, Farahzadi Blv, Shahrak Gharb
City
Tehran
Postal code
00982122357484
Phone
Fax
Email
a_hekmat2000@yahoo.com
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
MD, PhD/ Assistant Prof
Other areas of specialty/work
Street address
#7, West Arghavan, Farahzadi BLv, Shahrak Gharb
City
Tehran
Postal code
19437
Phone
+98 21 2235 7484
Fax
Email
a_hekmat2000@yahoo.com
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