Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the therapeutic effect of oral administration of cinnamon on Non-alcoholic steatohepatitis (NASH)

Protocol summary

Summary

Evaluation of the therapeutic effect of oral administration of cinnamon on Non-alcoholic steatohepatitis (NASH) Main objectives: The purpose of this study is to evaluate the therapeutic effect of cinnamon herbal medicine on non-alcoholic steatohepatitis, in comparison with vitamin E supplement. Design: Sixty patients voluntarily gave their signed informed consent and participated in this trial. Patients were divided into two thirty member groups by permutated block randomization. Inclusion and exclusion criteria: Patients who had no history of alcohol consumption or use of hepatotoxic drugs and other chronic hepatic or bile diseases, and also their disease has been diagnosed in ultrasonography and their ALT level was higher than 65 U/L, have been included in the study. If one of the volunteers during the study, becomes pregnant, indicates hypersensitivity reactions to cinnamon or by the end of the forth week has a rise in liver enzymes because of the medicine consumption, will be excluded from the study. Setting and conduct: At first, baseline laboratory tests were done and factors like liver enzymes level, especially ALT level, lipid profile and fasting blood sugar were measured and recorded. Interventions: For control group, a daily dose of 400 mg vitamin E, and for the other group, 250 mg of cinnamon, 4 times a day will be administered. Outcome measures: At the end of the forth and the eighth weeks the laboratory tests will be repeated and patients' lipid profile and liver enzymes level, especially ALT, will be measured. To get more compliance and evaluate probable adverse drug reactions, patients will be contacted weekly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062115587N9**

Registration date: **2016-02-18, 1394/11/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-18, 1394/11/29

Registrant information

Name

Nasrin Naseri

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4263

Email address

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Recruitment status

Recruitment complete

Funding source

Vice –Chancellor of Shiraz University of Medical Sciences, Shiraz, Iran

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of oral administration of cinnamon on Non-alcoholic steatohepatitis (NASH)

Public title

Effect of cinnamon on liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria of the study: ALT level higher than 65U/L; Diagnosed fatty liver in ultrasonography; No alcohol and drug abuse; No history of chemotherapy in the past years; No history of other chronic liver diseases such as hepatitis B and hepatitis C, cirrhosis, bile diseases, autoimmune diseases, cancer and any genetic disorder that effects liver function such as Wilson's disease; No history of lipid-lowering drug use; No pregnancy and breast-feeding; No use of vitamin E supplements; No use of drugs that caused fatty liver, like tetracycline, vitamin A, methotrexate, amiodarone, tamoxifen, etc.; No history of use of hepatotoxic drugs in the last 6 months; No long-term use of herbal drugs Exclusion criteria: If the patient indicates hypersensitivity reactions to cinnamon, becomes pregnant or not interested, and also if the level of liver enzymes rises at the end of the forth week due to cinnamon consumption, the patient will be excluded from the study.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients were divided into two 30 member groups by Permutated block randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Postal code

Approval date

2015-05-17, 1394/02/27

Ethics committee reference number

IR.SUMS.REC.1394.30

Health conditions studied

1

Description of health condition studied

Non-alcoholic steatohepatitis

ICD-10 code

K75.8

ICD-10 code description

nonalcoholic steatohepatitis

Primary outcomes

1

Description

Reduction in ALT serum level

Timepoint

Before intervention, at the end of the fourth week of intervention, at the end of the eighth week of intervention

Method of measurement

Blood test and laboratory kits

2

Description

Reduction in AST serum level

Timepoint

Before intervention, at the end of the fourth week of intervention, at the end of the eighth week of intervention

Method of measurement

Blood test and laboratory kits

Secondary outcomes

1

Description

Lipid profile improvement

Timepoint

Before intervention, at the end of the fourth week of intervention, at the end of the eighth week of intervention

Method of measurement

Blood test and laboratory kits

Intervention groups

1

Description

Intervention group: Patients will receive 250 mg

cinnamon capsules, prepared in Shiraz University of Medical Sciences, faculty of pharmacy, 4 times a day for two months. Related tests will be done at the beginning of the study and the end of every four weeks. To get more compliance and evaluate probable adverse drug reactions, patients will be contacted weekly. Control group: Will receive 400 mg Vitamin E capsule, once daily for two months. Related tests will be done at the beginning of the study and the end of every four weeks. To get more compliance and evaluate probable adverse drug reactions, patients will be contacted weekly.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive 400 mg Osve Vitamin E capsule, once daily for two months. Related tests will be done at the beginning of the study and the end of every four weeks. To get more compliance and evaluate probable adverse drug reactions, patients will be contacted weekly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Polyclinic

Full name of responsible person

Elham Mansourabadi

Street address

Motahari Polyclinic, Namazi Square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice –Chancellor of Shiraz University of Medical Sciences

Full name of responsible person

Seyyed Basir Hashemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice –Chancellor of Shiraz 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

Gastroenterohepatology Research Center of Shiraz

Full name of responsible person

Maryam Moeeni

Position

Gastroenterohepatology Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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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