Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The effect of citrulline supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patient with nonalcoholic fatty liver disease

Protocol summary

Summary

The main purpose: the effect of citrulline supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patients with nonalcoholic fatty liver randomized, double-blind, placebo-controlled inclusion criteria: age 18 years and above;Concentrations of liver enzymes ALT and AST greater than 1.5 times normal;Evidence of nonalcoholic steatohepatitis in Fibroscan Exclusion criteria:Not continue to cooperation;Those less than 10% supplemen at the end of the sixth and twelfth week consume. Summary of the project:In this study, patients with non-alcoholic fatty liver if they wish to participate in the study consent form them to be taken.After 12 to 14 hours of fasting, 5 cc of blood is taken to measure their blood serum concentrations of lipids, inflammatory factors and other serum biochemical parameters and kept in the freezer.Participants randomly using the divided randomly classified into two groups:supplement and placebo group.Patients group supplement recived daily 2 grams of citrulline for three months and Patients in the control group recived placebo daily 2 grams. At the end of the third months, anthropometric, dietary recall and serum is taken and with fibroscan, changes in the degree of hepatic steatosis recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703194010N18**
Registration date: **2017-10-13, 1396/07/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-13, 1396/07/21

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

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute Iran Iran University of Medical Sciences of Colorectal Research Center

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of citrulline supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patient with nonalcoholic fatty liver disease

Public title

investigate effect of citrulline in the treatment of non-

alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for the study: Age 18 and older;Concentrations of liver enzymes ALT and AST greater than 1.5 times normal;Evidence of nonalcoholic steatohepatitis in Fibroscan (Controlled Attenuation Parameter (CAP) score> 263);Have not a history of consumption alcohol more than 10 milligrams of per day for women and more than 20 mg per day for men;Not consume any dietary supplement in the past three months not consume any hepatotoxic drugs such as phenytoin, lithium Exclusion criteria: Not continue to cooperation;Biliary diseases; autoimmune and cancer and inherited disorders affecting liver during the study;Those less than 10% supplemen at the end of the sixth and twelth week consume.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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, Shahid Beheshti University of Medical Sci

Street address

West arghavan, Sanaat square, Farahzadi boulvard, Shahrake gharb

City

Tehran

Postal code

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.SBMU.nnftri.13950107

Health conditions studied

1

Description of health condition studied

non alcoholic fatty liver disease

ICD-10 code

(K75.8)

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

LDL-C

Timepoint

Being andend of intervention

Method of measurement

Enzymatic methods using kits

2

Description

HDL-C

Timepoint

Being andend of intervention

Method of measurement

Enzymatic methods using kits

3

Description

TG

Timepoint

Being andend of intervention

Method of measurement

Enzymatic methods using kits

4

Description

total Cholesterol

Timepoint

Being andend of intervention

Method of measurement

Enzymatic methods using kits

5

Description

FBS

Timepoint

Being andend of intervention

Method of measurement

Enzymatic methods using kits

6

Description

Fasting insulin

Timepoint

Being andend of intervention
Method of measurement
Radioimmunoassay µU/mL

7

Description
AST
Timepoint
Being andend of intervention
Method of measurement
Enzymatic methods using kits

8

Description
ALT
Timepoint
Being andend of intervention
Method of measurement
Enzymatic methods using kits µg/m

9

Description
HOMA
Timepoint
Being andend of intervention
Method of measurement
Calculation

10

Description
TNF-α
Timepoint
Being andend of intervention
Method of measurement
Elisa Pg/dl

11

Description
IL_6
Timepoint
Being andend of intervention
Method of measurement
Elisa Pg/dl

12

Description
steatosis
Timepoint
Being andend of intervention
Method of measurement
Ultrasonography Grade 0: absence of steatosis grade 1: mild steatosis grade 2: moderate steatosis grade 3: severe steatosis

Secondary outcomes

1

Description
Total energy intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire Kcal per day

2

Description
Carbohydrate intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

3

Description
Protein intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

4

Description
total fat intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

5

Description
SAFA intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

6

Description
PUFA intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

7

Description
MUFA intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

8

Description
total fiber intake
Timepoint
Beginning and end of intervention
Method of measurement
questionnaire gram per day

Intervention groups

1

Description
intervention group:2 gram citrulline per day for three months
Category
Treatment - Other

2

Description
placebo group:2 gram starche per day for three months
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Zahra Darabi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences, National Nutrition and Food Technology Research
Full name of responsible person
Azita Hekmatdoost
Street address
West arghavan, Sanaat square, Farahzadi boulvard, Shahrake gharb
City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences, National Nutrition and Food Technology Research
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Colorectal Research Center,IRAN University of Medical Sciences
Full name of responsible person
shahram agah
Street address
nyayesh street.rasol akram,hospital
City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Colorectal Research Center,IRAN University of Medical Sciences
Proportion provided by this source
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
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Azita Hekmatdoust
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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