Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Evaluating the effect of Resveratrol supplement on lipid profile, hepatic enzymes, inflammatory factors, and hepatic fibrosis in patients with Nonalcoholic Fatty Liver Disease (NAFLD)

Protocol summary

Summary

In this study, 50 patients with nonalcoholic steatohepatitis grade one or more will be randomly assigned to two groups receiving either resveratrol supplements or placebo for 12 weeks. Serum markers including blood lipids, liver enzymes, inflammatory markers and liver view in fibroscan and sonography will be measured before and after treatment and effects of resveratrol supplementation will be compared with placebo to determine the effects of resveratrol supplementation in the treatment of non-alcoholic fatty liver disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202014010N7**
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)

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute (NNFTRI)

Expected recruitment start date

2012-06-21, 1391/04/01

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

Evaluating the effect of Resveratrol supplement on lipid profile, hepatic enzymes, inflammatory factors, and hepatic fibrosis in patients with Nonalcoholic Fatty Liver Disease (NAFLD)

Public title

Evaluation of the effects of Resveratrol Supplementation on Hepatic Enzymes, Inflammatory Factors, Lipid profile, blood glucose, Insulin Sensitivity, and Hepatic fibrosis in patients with Nonalcoholic Fatty Liver Disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 and older; Evidence of nonalcoholic steatohepatitis with steatosis grade higher or equal to 1 in ultrasonography; No history of Alcohol consumption or consuming less than 10 grams alcohol per day in women and less than 20 grams per day in men; Absence of other liver disorders, malignancies, cardiovascular, respiratory, and kidney disorders;

Absence of pregnancy or lactation; Absence of taking any medications in the past three months; Absence of weight loss in the recent three months; Absence of endocrine and metabolism disorders. Exclusion criteria: Weight loss more than 10% of baseline body weight during the intervention period. Pregnancy; Disliking to continue 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: **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

Street address
West Arghavan, Farahzadi Blv, Shahrak Gharb

City
Tehran

Postal code

Approval date
2012-08-20, 1391/05/30

Ethics committee reference number
046468

Health conditions studied

1

Description of health condition studied
Non Alcoholic Fatty Liver

ICD-10 code
K75.9

ICD-10 code description
Inflammatory liver disease, unspecified

Primary outcomes

1

Description
Liver Enzymes

Timepoint
at the first and at the 12th week of the study

Method of measurement
Biochemical analysis

Secondary outcomes

1

Description
Liver fibrosis

Timepoint
at the first and the end of the study

Method of measurement
Fibroscan

Intervention groups

1

Description
Intervention: Soft gel Resveratrol 500 mg once a day /12 weeks

Category
Treatment - Drugs

2

Description
Placebo: Edible paraffin soft gelonce a day/ 12 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
NAFLD Clinic

Full name of responsible person

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Nutrition and Food Technology Research Institute

Full name of responsible person
Dr Majid Hajifaraji

Street address
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
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
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Full name of responsible person
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PHD/ Assistant Proffessor
Other areas of specialty/work
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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