

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

hekmat@sina.tums.ac.ir

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.

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

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)

Phone

+98 21 2293 0824

Email address

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**

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr Azita Hekmatdoost

Position

PHD/ Assistant Proffessor

Other areas of specialty/work**Street address**

West Arghavan, Farahzadi Blv, Shahrak Gharb

City

Tehran

Postal code**Phone**

+98 21 2236 0656

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

Full name of responsible person

Dr Azita Hekmatdoost

Position

PHD/ Assistant Proffessor

Other areas of specialty/work**Street address**

West Arghavan, Farahzadi Blv, Shahrak Gharb

City

Tehran

Postal code**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