Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of resveratrol supplementation, calorie restriction diet and placebo on nutritional status, metabolic and oxidative parameters, serum sirtuin-1 and fibroblast growth factor-21 levels in patients with nonalcoholic fatty liver disease

Protocol summary

Summary

The aim of this study is to investigate the effects of resveratrol supplementation compared with calorie restriction diet on nutritional status, metabolic and oxidative parameters, serum sirtuin-1 and fibroblast growth factor-21 levels in patients with nonalcoholic fatty liver disease. Eighty-seven patients will randomly be divided in to 3 intervention groups including: resveratrol group (receive 2 capsules each containing 300 mg trans resveratrol); calorie restriction diet group (receive a prescribed diet for the purpose of losing maximum 10 percent of their initial body weight); placebo group: (receive 2 capsules each containing 300 mg starch) for 12 weeks. Researcher and patients are blinded in resveratrol and placebo groups. BMI, age and sex will be matched in 3 groups. All patients will receive basic education about principles of healthy eating. At the baseline and the end of the intervention, biochemical indices, anthropometric and blood pressure measurements will be assessed and compared between groups. Three-day food record questionnaires and physical activity questionnaire will be fulfilled at baseline, after 6 weeks and end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511233664N16**
Registration date: **2016-02-08, 1394/11/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-08, 1394/11/19

Registrant information

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Name of organization / entity
Tabriz University Of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Nutrition Research Center, Vice-chancellor of Tabriz University of Medical Sciences.

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of resveratrol supplementation, calorie restriction diet and placebo on nutritional status, metabolic and oxidative parameters, serum sirtuin-1 and fibroblast growth factor-21 levels in patients with nonalcoholic fatty liver disease

Public title

Comparison of resveratrol supplementation and calorie restriction diet effects on nutritional and metabolic status in patients with nonalcoholic fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 20 to 60 years from both gender; diagnosed with nonalcoholic fatty liver disease based on liver Ultrasonography; BMI=25-35; willingness to participate in the study. Exclusion criteria: pregnancy; breast feeding and postmenopausal women; professional athletes; smoking; alcohol consumption; following weight-reducing diet 3 months prior to the study; known liver disease (viral/etc.); inherited disorders affecting the liver; history of diagnosed cardiovascular, kidney, diabetes, gastrointestinal, pulmonary and autoimmune diseases, thyroid dysfunction and active cancer; recent surgery; use of medications such as corticosteroids, hepatotoxic drugs, hormonal drugs (such as oral contraceptive and/or estrogens), antidepressants and psychotropic medications, anticoagulant drugs, oral anti-diabetic and lipid-lowering drugs. Receiving any kinds of supplements 3 months prior to the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This study is partially blinded. The intervention for resveratrol and placebo groups is indistinguishable for study subjects in those two groups. Randomization was carried out using a random allocation software (RAS).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code

Approval date

2015-12-15, 1394/09/24

Ethics committee reference number

TBZMED.REC.1394.823

Health conditions studied

1

Description of health condition studied

nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

liver enzymes (ALT, AST, GGT, ALP)

Timepoint

Baseline and after the intervention

Method of measurement

Spectrophotometry

2

Description

Liver echogenicity

Timepoint

Baseline and after the intervention

Method of measurement

Sonographic findings

3

Description

lipid profile (TC, TG, LDL-C, HDL-C, APO-A1, APO-B)

Timepoint

Baseline and after the intervention

Method of measurement

Biochemical

4

Description

Fasting blood glucose

Timepoint

Baseline and after the intervention

Method of measurement

Biochemical

5

Description

Insulin

Timepoint
Baseline and after the intervention
Method of measurement
ELISA

6

Description
Insulin resistance
Timepoint
Baseline and after the intervention
Method of measurement
HOMA-IR

7

Description
Oxidative status (TAC, MDA, GPx, SOD, Ox-LDL)
Timepoint
Baseline and after the intervention
Method of measurement
Biochemical

8

Description
Sirtuin-1
Timepoint
Baseline and after the intervention
Method of measurement
ELISA

9

Description
Fibroblast growth factor-21
Timepoint
Baseline and after the intervention
Method of measurement
ELISA

10

Description
Added at 2016-11-15: Plasminogen activator inhibitor-1 (PAI-1
Timepoint
Added at 2016-11-15: Baseline and after the intervention
Method of measurement
Added at 2016-11-15: ELISA

11

Description
Added at 2016-11-15: hs-CRP
Timepoint
Added at 2016-11-15: Baseline and after the intervention
Method of measurement
Added at 2016-11-15: Imonotorbidometry

Secondary outcomes

1

Description
systolic and diastolic blood pressure
Timepoint
Baseline and after the intervention
Method of measurement
Manometer

2

Description
Anthropometric measurements (BMI, WHR, WC)
Timepoint
Baseline and after the intervention
Method of measurement
Secca scale, non stretch meter

3

Description
Energy and nutrient intake
Timepoint
Baseline, end of week 6 and after the intervention
Method of measurement
3-day food record questionnaire

Intervention groups

1

Description
Intervention1: calorie restriction diet for 3 months
Category
Lifestyle

2

Description
Intervention 2: 2 capsules daily each contains 300 mg of trans resveratrol for 3 months
Category
Treatment - Drugs

3

Description
placebo: 2 capsules daily each contains 300 mg of starch for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golgashti clinic
Full name of responsible person
Dr. Mohammad Hossein Somi
Street address
Azadi street

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutrition Research Center, vice-chancellor of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Alireza Ostadrahimi
Street address
Faculty of Nutrition, Tabriz University of Medical Sciences, Golgasht street
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition Research Center, vice-chancellor of Tabriz 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

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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