

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

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

rafrafm@tbzmed.ac.ir

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

City
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

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Somayyeh Asghari

Position
Ph.D Candidate in Nutrition Sciences

Other areas of specialty/work

Street address
Nutrition Faculty, Tabriz University of Medical
Sciences, Golgasht street

City
Tabriz

Postal code

Phone
+98 914 423 7085

Fax

Email
sasghari@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Maryam Rafraf

Position
Ph.D in Nutrition Sciences

Other areas of specialty/work

Street address
Nutrition Faculty, Tabriz University of Medical
Sciences, Golgasht street

City
Tabriz

Postal code

Phone
+98 41 3335 7580

Fax

Email
rafrafm@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Somayyeh Asghari

Position
Ph.D Candidate in Nutrition Sciences

Other areas of specialty/work

Street address
Nutrition Faculty, Tabriz University of Medical
Sciences, Golgasht street

City
Tabriz

Postal code

Phone
+98 41 3335 7581

Fax

Email
sasghari@tbzmed.ac.ir

Web page address

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