

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effects of Rosemary (*Rosmarinus officinalis*) Leaves Powder And Weight Reducing Diet on Hs-CRP, MDA, TAC, Blood Pressure, Anthropometric measurement, Quality of life, Sleep and Appetite in Patients with Non-Alcoholic Fatty Liver Disease

#### Protocol summary

##### Study aim

Evaluation of the effect of rosemary leaves consumption with weight loss diet on Hs-CRP, malondialdehyde, total antioxidant capacity, blood pressure, anthropometric indices, quality of life, sleep and appetite in patients with non-alcoholic fatty liver

##### Design

Study Type: Double-blind Randomized Clinical Trial. Sample size: 120 people (based on body mass index and 95% confidence interval, 80% test power and 10% prediction of sample loss). Groups: 1) Intervention (n = 60): receive 4 grams of rosemary powder daily with weight loss diet. 2) Control (60 people): Get 4 grams of starch daily with weight loss diet. Duration of intervention: 8 weeks. Sampling Method: Available Randomization: Using random blocks (30 blocks of 4 according to the sample size of 120). Hide: Use unique code on sachets Study phase: 2

##### Settings and conduct

The present study was a randomized, double-blind clinical trial of 8 weeks in patients with non-alcoholic fatty liver referring to the Gastroenterology and Liver Clinic of Razi Hospital in Rasht, which is based on the approval of a specialist and preliminary studies with inclusion criteria. will be done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction, 1 to 3 degrees of nonalcoholic fatty liver, increased liver enzymes than normal, body mass index above normal, adult Exclusion criteria: Conditions leading to hepatic steatosis, use of any dietary supplement and weight-loss medication, severe weight loss diet, smoking, pregnancy, or lactation

##### Intervention groups

1: Intervention (n = 60): daily consumption of 4 grams of rosemary leaf powder with weight loss diet and physical activity recommendation 2: Control (n = 60): receive 4

grams of starch with weight loss diet and exercise recommendation

##### Main outcome variables

High sensitivity C-reactive protein, malondialdehyde, total antioxidant capacity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120415009472N19**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

##### Registration date

2019-10-14, 1398/07/22

##### Registrant information

##### Name

Naheed Aryaeian

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

aryaeian.n@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01  
**Expected recruitment end date**  
2020-04-20, 1399/02/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Effects of Rosemary (Rosmarinus officinalis) Leaves Powder And Weight Reducing Diet on Hs-CRP, MDA, TAC, Blood Pressure, Anthropometric measurement, Quality of life, Sleep and Appetite in Patients with Non-Alcoholic Fatty Liver Disease

**Public title**  
Effects of Rosemary (Rosmarinus officinalis) Leaves Powder And Weight Reducing Diet on Hs-CRP, MDA, TAC, Blood Pressure, Anthropometric measurement, Quality of life, Sleep and Appetite in Patients with Non-Alcoholic Fatty Liver Disease

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Desire to participate in studying and signing consent  
Evidence of hepatic steatosis in liver ultrasonography (grade 1 to 3 fatty liver) Increased liver enzymes than normal (AST> 38 and ALT> 40 for men and AST> 31 and ALT> 33 for women) BMI in the range of 25-40 kg / m2 aged between 20 and 65 years

**Exclusion criteria:**

Unwillingness to participate in the study Secondary conditions that lead to hepatic steatosis, including: alcohol consumption, hereditary disorders affecting liver status (hemochromatosis and Wilson's disease), and known autoimmune disease Other chronic and acute liver diseases and disorders such as hepatitis, cirrhosis, celiac disease, diabetes, thyroid disorders, cardiovascular, renal, pulmonary and inflammatory diseases (rheumatism) History of taking hepatotoxic drugs (methotrexate, amiodarone, tamoxifen, nifedipine, corticosteroids, valproate and antiviral drugs) as well as anticoagulants such as aspirin Use of any nutritional supplement in the past two months Use of weight-loss drugs over the past two months Having a severe weight loss diet (more than 10% weight loss) over the past three months smoking Pregnancy or lactation

**Age**  
From **20 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, patients referred to the Gastroenterology and Liver Clinic of Razi Hospital in Rasht will be selected by available sampling method. For randomization, the permuted block randomization will be used with 4 blocks. According to the sample size of 120, 30 blocks of 4 will be produced using the online site (www.sealedenvelope.com).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to apply concealment in the randomization process, unique code will be used on the sachets that the code will generate by the software. As each individual enters the study, based on the sequence generated, the powder containing the code in which the code is intended will be assigned to the individual, and the rosemary or placebo powder will be coded by a third party who is unaware of the contents of the sachets. It is randomly divided into two groups by the above method. None of the patients, as well as the researcher, will be aware of the group in which the patients will be placed and the type of intervention (rosemary or placebo).

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Sheikh Fazlollah and Chamran Intersection, Hemmat Highway, Iran University of Medical Sciences, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2019-08-31, 1398/06/09

**Ethics committee reference number**

IR.IUMS.REC.1398.495

## 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

Malondialdehyde

#### Timepoint

Before intervention and 8 weak after intervention

#### Method of measurement

Colorimetric method

### 2

#### Description

Total Antioxidant Capacity

#### Timepoint

Before intervention and 8 weak after intervention

#### Method of measurement

Colorimetric method

### 3

#### Description

High sensitivity C-reactive protein

#### Timepoint

Before intervention and 12 weak after intervention

#### Method of measurement

Turbidometric method

## Secondary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

Before intervention and 8 weak after intervention

#### Method of measurement

Mercury barometric

### 2

#### Description

Diastolic blood pressure

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

Mercury barometric

### 3

#### Description

Weight

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

Scales

### 4

#### Description

Waist

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

Meter

### 5

#### Description

Hip circumference

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

Meter

### 6

#### Description

Waist to hip ratio

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

calculation

### 7

#### Description

Body fat percentage

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

inbody

### 8

#### Description

BMI

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

calculation

### 9

#### Description

Quality of Life

#### Timepoint

Before intervention and 8 months after intervention

#### Method of measurement

SF-36 questionnaire

## 10

### **Description**

sleep quality

### **Timepoint**

Before intervention and 8 months after intervention

### **Method of measurement**

The Pittsburgh Sleep Quality questionnaire

## 11

### **Description**

Appetite

### **Timepoint**

Before intervention and 8 months after intervention

### **Method of measurement**

CNAQ questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group (n = 60): Low-calorie diet and physical activity design based on the Adult Overweight and Obesity Control Guide (published by the US National Heart, Lung, and Blood Institute). The low-calorie diet will be calculated as 500 kcal less than the energy needed by each patient, and the macronutrient division is calculated as 30% fat, 15% protein and 55% carbohydrate. The diet will be adjusted according to the amount of units needed for each individual diet and a list of food substitutes will be explained. Physical activity is also recommended to all patients for at least 3 days a week. Diet adherence and physical activity will be assessed weekly through telephone interviews as well as using dietary intake records and 24-hour physical activity at the beginning and end of the study (35). The intervention group also received 4 grams of rosemary leaf powder daily.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group (n = 60): Low-calorie diet and physical activity similar to the intervention group with 4 grams of starch powder (placebo) daily.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Medical and Research Center of Razi Hospital in Rasht

##### **Full name of responsible person**

Saeedeh ebrahimpzadeh

##### **Street address**

Razi Street, Razi Medical Training Center, Rasht, Iran

#### **City**

Rasht

#### **Province**

Guilan

#### **Postal code**

41448

#### **Phone**

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#### **Email**

razi.hospital@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice-chancellor for research Iran University of Medical Sciences

##### **Full name of responsible person**

Dr Ali Javad Moosavi, Assistant of Research and Technology, Iran University of Medical Sciences

##### **Street address**

Iran University of Medical Sciences, The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat highway

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

+98 21 86701

##### **Email**

admins@iums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Vice-chancellor for research Iran University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Dr Nahid Aryaeian

**Position**

Phd in Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

School of health, Iran University of Medical Sciences, the intersection of Sheikh Fazlallah and Chamran, Shahid Hemmat highway

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n-aryaeian@sina.tums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Naheed Aryaeian

**Position**

Professor Assistant / Nutrition PhD.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

saeedeh ebrahimzadeh

**Position**

MS Student in Health Sciences in Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition, School of health, Iran University of Medical Sciences, The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat highway

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saeedeh.7272.eb@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Only a section of the data, such as primary outcomes information or the like, will be shared.

**When the data will become available and for how long**

Access period start 6 months after results publishing.

**To whom data/document is available**

The obtained data from current study will be available only for working researchers in academic and scientific institutions.

**Under which criteria data/document could be used**

Six months after the published papers from this study, the obtained data will be available to the researchers for further analysis.

**From where data/document is obtainable**

Applicants can be communicated to correspond author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of Public Health, Iran university of Medical Sciences, Hemat Express way, Tehran Cell phone:+98 21 8670 4743 Email:n-aryaeian@sina.tums.ac.ir

**What processes are involved for a request to access data/document**

publishing in scientific- research journals Applicants will be given access to the obtained data from current study by sending an email to the correspond author.

**Comments**