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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

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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 publicated 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