Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Oct 2026

Effects of Rosemary (Rosmarinus officinalis) Leaves Powder And Weight Reducing Diet on Lipid Profile, Glycemic Status And Liver Enzymes in Patients with Non-Alcoholic Fatty Liver Disease

Protocol summary

Study aim

Effects of Rosemary (Rosmarinus officinalis) Leaves Powder And Weight Reducing Diet on Lipid Profile, Glycemic Status And Liver Enzymes in Patients with Non-Alcoholic Fatty Liver Disease

Design

A double-blind randomized clinical trial with 120 patients (60 patients in intervention and 60 controls) with nonalcoholic fatty liver

Settings and conduct

120 patients with inclusion criteria who are referred to Razi Gastroenterology Research Center of Razi Hospital in Rasht will be selected randomly (intervention or control). be. Also at the beginning and end of the study, anthropometric indices and questionnaires related to personal information, physical activity measurement, and 24-hour recall will be completed through interview. To make the study double-blind, unique codes will be used on the sachets in the randomization process, and the placebo sachets will have the same interior and exterior appearance as the rosemary sachets, and none of the participants and researchers from the group Where they will be placed and the type of intervention (rosemary powder or placebo) will not know

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

60 patients in intervention group received 4 grams of rosemary powder daily with weight loss diet and physical activity recommendation for 8 weeks, while 60 patients in control group received 4 grams of starch with weight loss diet and physical activity recommendation for 8 weeks.

Main outcome variables

ALT , AST , ALP , GGT , TG , TC , LDL-C , HDL-C , FBS , Insulin , HOMA-Insulin resistance , HOMA- β% , QUICKI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N20**
Registration date: **2019-11-12, 1398/08/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-12, 1398/08/21**
Update count: **0**

Registration date

2019-11-12, 1398/08/21

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4750

Email address

aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

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 Lipid Profile, Glycemic Status And Liver Enzymes in Patients with Non-Alcoholic Fatty Liver Disease

Public title
Effects of Rosemary (Rosmarinus officinalis) Leaves Powder And Weight Reducing Diet on Lipid Profile, Glycemic Status And Liver Enzymes in Patients with Non-Alcoholic Fatty Liver Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Desire to participate in studying and signing consent Diagnosis of non-alcoholic fatty liver according to criteria of the American Gastroenterology Association (33): Evidence of hepatic steatosis in liver ultrasound (grade 1 to 3 fatty liver), ALT and AST increased than normal (AST> 38 and ALT> 40 for men and more than 31 and 33 for women), the absence of conditions or diseases secondary to hepatic steatosis, including: alcohol consumption, hereditary disorders affecting liver status (hemochromatosis and Wilson's disease), Known autoimmune disease, history of hepatotoxic drugs (methotrexate, aminodarone, tamoxifen, nifedipine, corticosteroids, valproate, and medications) The virus) and non-use of anticoagulant drugs such as aspirin. Not getting other diseases and chronic and acute liver disorders (hepatitis B, C, etc.), cirrhosis, celiac disease, diabetes, thyroid disorders, cardiovascular, kidney, pulmonary and inflammatory diseases (rheumatism) BMI in the range of 40-25 Kg / m2 The age range is 20 to 65 years No use of any nutritional supplements in the past two months No use of weight-effective drugs over the past two months Not having a weight loss diet (a decrease of more than 10% of the weight) over the past three months Do not use drugs and cigarettes No pregnancy or lactation
Exclusion criteria:
Secondary conditions that lead to hepatic steatosis, including: alcohol consumption, hereditary disorders affecting liver status (hemochromatosis and Wilson's disease), and known autoimmune diseaseOther 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

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 120 subjects, 30 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug sachets that is generated by the software. Participants will enter based on the sequence produced into study and the drug sachets with code registered will allocate to the individual. Therefore, before participants selection, they will be unaware of the type of intervention that will receive,as well as the researcher, and random sequence produced during the study will be immune from prediction.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to perform a double-blind study in order to apply concealment in the randomization process, unique codes 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 participants, as well as the researcher, will be aware of the group (rosemary or placebo powder) that will be included and the type of intervention (rosemary or placebo powder) and the powder containing cartridges as well as the placebo and rosemary cartridges. They will be similar in appearance and exterior.
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
Shahid Hemmat Highway intersection of Sheikh Fazlollah and Shahid Chamran Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2019-09-24, 1398/07/02
Ethics committee reference number
IR.IUMS.REC.1398.656

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
ALT
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Colorimetric method

2

Description
AST
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Colorimetric method

3

Description
ALP
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Colorimetric method

4

Description
GGT
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Colorimetric method

5

Description
TG
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Enzyme colorimetric method

6

Description
TC
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Enzyme colorimetric method

7

Description
HDL-C
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Enzyme colorimetric method

8

Description
FBS
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
Enzymatic calorie meter method

9

Description
Insulin
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
ELISA

10

Description
LDL-C
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
calculation

11

Description
HOMA-Insulin resistance
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
calculation

12

Description
HOMA- β%
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
calculation

13

Description
QUICKI
Timepoint
Before intervention and 8 weak after intervention
Method of measurement
calculation

Secondary outcomes

1

Description
Weight
Timepoint
Before intervention and 8 months after intervention
Method of measurement
Scales

2

Description
Height
Timepoint
Before intervention and 8 months after intervention
Method of measurement
Meter

3

Description
Waist
Timepoint
Before intervention and 8 months after intervention
Method of measurement
Meter

4

Description
BMI
Timepoint
Before intervention and 8 months after intervention
Method of measurement
calculation

Intervention groups

1

Description
Intervention group A (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 energy required for each patient is calculated and the macronutrient division is calculated as 30% fat, 15% protein and 55% carbohydrate. The diet will be adjusted based on the amount of units needed for each individual food group and a list of food substitutes will be explained. Physical activity is also recommended to all patients for at least 150 minutes per week. Adherence to the prescribed diet and physical activity are monitored weekly through telephone interviews as well as using dietary intake records and 24-hour physical activity at the beginning and end of the study (34). The intervention group also received 4 grams of rosemary leaf powder daily.
Category
Treatment - Drugs

2

Description
Control group B (n = 60): Low-calorie diet and physical activity similar to group A receive 4 grams of starch powder (placebo).
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
Shayan Akbari
Street address
Sardar Jangal
City
Rasht
Province
Guilan
Postal code
-
Phone
+98 13 3353 5116
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 Seyed Abbas Motevalian

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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 86701

Email
adminsite@iums.ac.ir

Web page address

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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8877 9118

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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8877 9118

Email
n-aryaeian@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Shayan Akbari

Position
MS Student 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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701
Email
shayanakb72@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 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
-