

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Rosemary (*Rosmarinus officinalis*) leaves powder on glycemic indexes, lipid profile, total antioxidant capacity, SOD, GSH-Px and hs-CRP in patients with type 2 diabetes

Protocol summary

Study aim

Effect of Rosemary (*Rosmarinus officinalis*) leaves powder on Glycemic indexes, Lipid profile, Total Antioxidant capacity, SOD, GSH-Px and hs-CRP in Patients with Type 2 Diabetes

Design

A double-blind randomized clinical trial with 90 patients with Type 2 diabetes. Randomization with Using random blocks.

Settings and conduct

In this study, 90 Patients with Type 2 Diabetes referred to the Endocrinology Clinic of Imam Khomeini Hospital will be divided into two intervention or control groups and will be followed for 12 weeks. All Laboratory tests, anthropometric indices and blood pressure will be measured at the beginning of the study and at the end of the twelfth week. 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; diagnosis of Type 2 Diabetes; at least one year of history of Diabetes; age range 25 to 70 years old; do not take any antioxidant and dietary supplements during last 2 months; no pregnancy and lactation; no other chronic and inflammatory diseases. Exclusion criteria: alcohol consumption; smoking any drugs; Insulin use; any allergies.

Intervention groups

1: Intervention (n=45): daily consumption of 4 grams of rosemary leaf powder with diet recommendation 2: (n=45): receive 4 grams of starch with diet

recommendation

Main outcome variables

Fasting blood sugar; fasting insulin; insulin resistance; quantitative insulin sensitivity check index; total serum cholesterol and triglyceride; HDL-C, LDL-C; total antioxidant capacity; SOD; GSH-PX; high sensitivity C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N23**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **prospective**

Last update: **2021-01-02, 1399/10/13**

Update count: **0**

Registration date

2021-01-02, 1399/10/13

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

2021-04-21, 1400/02/01
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Rosemary (Rosmarinus officinalis) leaves powder on glycemic indexes, lipid profile, total antioxidant capacity, SOD, GSH-Px and hs-CRP in patients with type 2 diabetes

Public title
Effect of Rosemary (Rosmarinus officinalis) leaves powder in type 2 diabetes patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study and signing of the consent form
Diagnosis of type 2 diabetes (fasting blood sugar higher than or equal to 126mg / dl or two hours above 200mg / dl or random blood sugar above 200 with one of the symptoms of hyperglycemia or hyperlipidemia)
At least one year of history of diabetes (diagnosis of diabetes based on a doctor's opinion)
Serum triglyceride above 200 mg / dl. Age range 25 to 70 years old
Their body mass index is 20-35
Do not take any antioxidant and dietary supplements during the last 2 months
Not getting pregnant and breastfeeding
Do not have other chronic and inflammatory diseases

Exclusion criteria:

Smoking and any Drugs
Cardiovascular, renal or liver diseases
Use any antioxidant and dietary supplement during the last two months
Use of Insulin
Alcohol consumption
Any allergies (gastrointestinal or skin) to any antioxidant or multivitamin supplement

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomized allocation performing, permuted block randomization will be used by blocks. According to the sample size of 90 subjects, 15 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 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. Its 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) 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

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

City

Tehran

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Postal code

1449614535

Approval date

2020-12-26, 1399/10/06

Ethics committee reference number

IR.IUMS.REC.1399.1057

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar (FBS)

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

2

Description

Fasting insulin

Timepoint

Before intervention and 12 week after intervention

Method of measurement

ELISA

3

Description

LDL-C

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

4

Description

HDL-C

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

5

Description

Total triglyceride

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

6

Description

Total cholesterol

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

7

Description

HOMA- Insulin resistance

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calculation

8

Description

Quantitative insulin sensitivity check index (QUICKI)

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calculation

9

Description

High sensitivity C-reactive protein

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Immunoturbidimetric method

10

Description

Total Antioxidant Capacity

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

11

Description

Superoxide dismutase (SOD)

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

12

Description

Glutathione peroxidase (GSH-PX)

Timepoint

Before intervention and 12 week after intervention

Method of measurement

Calorie meter method

Secondary outcomes

1

Description

Weight
Timepoint
Before intervention and 12 week after intervention
Method of measurement
scales

2

Description
Height
Timepoint
Before intervention and 12 week after intervention
Method of measurement
meter

3

Description
Waist
Timepoint
Before intervention and 12 week after intervention
Method of measurement
Meter

4

Description
Body Mass Index (BMI)
Timepoint
Before intervention and 12 week after intervention
Method of measurement
Calculation

5

Description
Systolic blood pressure
Timepoint
Before intervention and 12 week after intervention
Method of measurement
Digital barometric

6

Description
Diastolic blood pressure
Timepoint
Before intervention and 12 week after intervention
Method of measurement
Digital barometric

7

Description
Physical activity
Timepoint
Before intervention and 12 week after intervention
Method of measurement
International Physical Activity Questionnaire (IPAQ)

8

Description
Total energy intake

Timepoint
Before intervention and 12 week after intervention
Method of measurement
24 hour recall questionnaire

9

Description
Micronutrients and Macronutrients intake
Timepoint
Before intervention and 12 week after intervention
Method of measurement
24 hour recall questionnaire

Intervention groups

1

Description
Intervention group (n=45): all patients receive relevant dietary recommendations and are asked not to change their diet and physical activity. Also, the participants of the intervention group receive 4 grams of rosemary leaf powder daily in the form of 2 sachets of 2000 mg (2 times a day) for 12 weeks and consume it in yogurt , buttermilk and salad. Rosemary sachets are provided by Green Plants of Life Company.

Category
Treatment - Drugs

2

Description
Control group (n=45): all patients receive relevant dietary recommendations and are asked not to change their diet and physical activity. Also, the participants of the control group receive 4 grams of starch daily in the form of 2 sachets of 2000 mg (2 times a day) for 12 weeks and consume it in yogurt, buttermilk and salad. Starch sachets are provided by Green Plants of Life Company.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology Clinic of Imam Khomeini Hospital in Tehran
Full name of responsible person
Mahsa Nateghi
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1419733141

Phone

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Email

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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, Hemmat Highway

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

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

P.h.D 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 Shahid Chamran, Hemmat Highway

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Nahid Aryaeian

Position

Professor Assistant/ Nutrition P.h.D

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mahsa Nateghi

Position

MS student in nutrition science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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m.nateghi2014@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 Highway, Tehran Cell phone: +982186704743 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 correspond author.

Comments