Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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

Province

Tehran

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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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
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Iran University of Medical Sciences, The intersection of Sheikh Fazlallah and Shahid Chamran, Hemmat Highway
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1449614535
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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
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
Mahsa Nateghi
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MS student in nutrition science
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Bachelor
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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 be 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