Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the efficacy of Lactobacillus rhamnosum and inulin supplements (alone and in combination) in inflammatory markers, oxidative stress, microbial transport, intestinal metabolites and gene expression of endocannabinoid CB1 and CB2 receptors in patients with coronary artery disease

Protocol summary

Study aim
The purpose of this study was to evaluate the effects of Lactobacillus rhamnosine and inulin supplementation (alone and in combination) in patients with coronary artery disease under weight loss diet.

Design
Randomized double-blind clinical trial with four arm parallel groups

Settings and conduct
The trial will be conducted at Imam Ali Hospital of Kermanshah University of Medical Sciences. Individuals who are willing to participate in the study will be evaluated to meet the inclusion criteria. They are then asked to complete an informed consent form. A third party blind to the study will deliver sequences extracted from the random allocation software. After nocturnal fasting, blood samples will be collected and supplements will be delivered to participants. The duration of the supplementary period will be 8 weeks.

Participants/Inclusion and exclusion criteria
96 patients with coronary stenosis will be included in the study. Patients with heart failure (FC III, IV) or cardiac output less than 30% will be excluded.

Intervention groups
Intervention group: Patients in this group will receive pro-inulin or probiotic supplements or their combination for 8 weeks. Inulin will be given in 10 grams of medicated sachets and the target group will consume once daily after lunch. Lactobacillus rhamnosus will be provided as pharmaceutical capsules 1.6× 10^10 colony forming units (CFU) and the target group will take one capsule daily after meals. Control group: Patients in this group receive an injection of maltodextrin daily with inulin and a placebo capsule containing maltodextrin as Lactobacillus rhamnose for 8 weeks.

Main outcome variables
Lipid profile, inflammatory factors, oxidative stress, endothelial serum markers, microbial transport levels and intestinal metabolites (including LPS, TLR-4 and TMAO) and expression of endocannabinoid CB1 and CB2 receptors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180712040438N4**
Registration date: **2020-03-10, 1398/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-10, 1398/12/20**
Update count: **0**

Registration date
2020-03-10, 1398/12/20

Registrant information

Name
Jalal Moludi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3335 2148

Email address
jmoludi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20
Expected recruitment end date
2020-05-09, 1399/02/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of Lactobacillus rhamnosum and inulin supplements (alone and in combination) in inflammatory markers, oxidative stress, microbial transport, intestinal metabolites and gene expression of endocannabinoid CB1 and CB2 receptors in patients with coronary artery disease

Public title
Effect of Lactobacillus rhamnosus and inulin supplements (alone and in combination) in patients with coronary artery disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with coronary artery stenosis body mass index is between 25-35 kg/m2
Exclusion criteria:
Heart failure or cardiac output less than 30% Supplement intolerance Patient decision to exclude study
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
From among the patients who volunteer to participate in the study, 96 individuals will be selected by simple random sampling. Then by using the Random Allocation Software, the subjects will be allocated into one of the groups of inulin, probiotic, inulin-probiotic combination or placebo, stratified by sex and age. The sequence of randomization will be kept in a safe place by an independent party and is not aware of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, no patient and investigator will be aware of the treatment assignments for the duration of the study. For blinding the trial, the Capsules , will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Faculty of Nutrition and Food Technology, Next to Farabi Hospital, Kermanshah, Iran , Postcode: 6719851552
City
Kermanshah
Province
Kermanshah
Postal code
6719851552
Approval date
2020-02-04, 1398/11/15
Ethics committee reference number
IR.KUMS.REC.1398.1065

Health conditions studied

1

Description of health condition studied
Coronary stenosis
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
vascular cell adhesion molecule 1
Timepoint
Baseline and 8 week after intervention
Method of measurement
ELISA

2

Description
Intercellular Adhesion Molecule 1
Timepoint

Baseline and 8 week after intervention

Method of measurement

ELISA

3

Description

Toll-like receptor 4

Timepoint

Baseline and 8 week after intervention

Method of measurement

ELISA

4

Description

Lipopolysaccharides

Timepoint

Baseline and 8 week after intervention

Method of measurement

ELISA

5

Description

Trimethylamine N-oxide

Timepoint

Baseline and 8 week after intervention

Method of measurement

ELISA

6

Description

Interlukin-6

Timepoint

Baseline and 8 week after intervention

Method of measurement

ELISA

7

Description

High-sensitivity C-reactive Protein

Timepoint

Baseline and 8 week after intervention

Method of measurement

ELISA

8

Description

Cannabinoid receptor type 1

Timepoint

Baseline and 8 week after intervention

Method of measurement

gene expression

9

Description

Cannabinoid receptor type 2

Timepoint

Baseline and 8 week after intervention

Method of measurement

gene expression

10

Description

malondialdehyde

Timepoint

Baseline and 8 week after intervention

Method of measurement

spectrophotometry

11

Description

total antioxidant capacity

Timepoint

Baseline and 8 week after intervention

Method of measurement

spectrophotometry

12

Description

Depression

Timepoint

Baseline and 8 week after intervention

Method of measurement

Beck questionnaire

13

Description

Quality of Life

Timepoint

Baseline and 8 week after intervention

Method of measurement

McNew Questionnaire

Secondary outcomes

1

Description

assessment of gut microbiota

Timepoint

At the baseline and after intervention

Method of measurement

Via real time PCR

Intervention groups

1

Description

Patients in this group will receive pro-inulin and probiotic supplements for 8 weeks. Inulin will be given in 10 grams of medicated sachets and the target group will consume once daily after lunch. Lactobacillus rhamnosus will provide 1.6× 10^10 colony forming units (CFU) bacterial drug capsules and the target group will consume one capsule daily. To ensure supplement consumption,

patients will be contacted weekly. The Quality of Life Questionnaire (McNEW) and Depression Inventory (Beck) were also completed

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group will receive pro-inulin supplement for 8 weeks. Inulin will be given in 10 grams of medicated sachets and the target group will consume once daily after lunch. In addition, a placebo capsule containing maltodextrin as a placebo for Lactobacillus rhamnosus will consume one post-meal daily. To ensure supplement consumption, patients will be contacted weekly. The Quality of Life Questionnaire (McNEW) and Depression Inventory (Beck) were also completed

Category

Treatment - Drugs

3

Description

Intervention group: Patients in this group will receive probiotic supplements for 8 weeks. Lactobacillus rhamnosus will provide 1.6× 10^10 colony forming units (CFU) bacterial drug capsules and the target group will consume one capsule daily. In addition, they will consume a single dose of maltodextrin replacement inulin daily after lunch. To ensure supplement consumption, patients will be contacted weekly. The Quality of Life Questionnaire (McNEW) and Depression Inventory (Beck) were also completed

Category

Treatment - Drugs

4

Description

Control group: Patients in this group receive an injection of maltodextrin daily with inulin and a placebo capsule containing maltodextrin as Lactobacillus rhamnose for 8 weeks. Placebo capsules are similar in appearance to probiotic capsules and to sachets, similar to inulin-containing sachets, and are difficult to distinguish.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Dr. Jalal Moloudi

Street address

Emam Ali Hospital, Shahid Beheshtir Boulevard , Postcode: 6715847145

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Kermanshah

Province

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Postal code

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Email

jmoludi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Faculty of Nutrition and Food Technology, Next to Farabi Hospital

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6719851552

Phone

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Email

farid_n32@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Jalal Moloudi

Position

Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Nutrition
Street address
Faculty of Nutrition and Food Technology, Next to Farabi Hospital
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6719851552
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr Jalal Moludi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Dr Jalal Moludi
Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared
When the data will become available and for how long
Accessibility to data is possible 8 months after publication.
To whom data/document is available
The data will only be available for people working in academic institutions.
Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting Meta analysis
From where data/document is obtainable
Dr Jalal Moludi, Faculty of Nutrition Sciences and Food Technology, Kermanshah University of Medical Sciences, +989399516760, jmoludi@yahoo.com
What processes are involved for a request to access data/document
Any one who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All these steps will not take more than 10 days.
Comments