Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Lactobacillus rhamnosus supplementation on inflammatory and oxidative biomarkers, gut microbiota profile, gut metabolites and cardiac remodeling in patients with Myocardial Infarction (MI)

Protocol summary

Study aim

To determine whether weight loss diet with or without Lactobacillus rhamnosus supplementation on inflammatory and oxidative biomarkers, gut microbiota profile, gut metabolites and cardiac remodeling in patients with Myocardial Infarction (MI).

Design

Randomized double-blind clinical trial with two arm parallel groups phase 3 trial

Settings and conduct

The trial will be conducted at outpatient cardiology clinic of Shahid Madani Heart center affiliated to Tabriz University of Medical Sciences, Iran. All the patients will be screened by an expert cardiologist for eligibility. Those willing to take part in the study will be carefully evaluated with reference to inclusion criteria. Then, they will be requested to sign an informed consent. A third party who is blind to the study will give the sequence extracted from allocation software. After an overnight fasting, blood will be collected and supplements will be provided to the participants. supplementation duration will be 12 weeks.

Participants/Inclusion and exclusion criteria

forty eight patients with Myocardial Infarction (MI) will be included in the study. Subjects with diabetes; chronic renal failure and history of supplementation with prebiotics will not be included.

Intervention groups

The subjects in both groups will receive a weight loss diet. Patients in the intervention group will use a Lactobacillus rhamnosus capsules 1.6 ×109 with their lunch, daily. In the placebo (control) group, the capsules will contain of maltodextrin.

Main outcome variables

Physical activity level, Depression level, Quality of Life, echocardiography in terms of cardiac remodeling,, serum levels of antioxidant capacity, lipid profile, inflammatory markers,gut microbiota profile and gut metabolite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121028011288N15**
Registration date: **2018-06-27, 1397/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-27, 1397/04/06**
Update count: **0**

Registration date

2018-06-27, 1397/04/06

Registrant information

Name
Mohammad Alizadeh
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Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Lactobacillus rhamnosus supplementation on inflammatory and oxidative biomarkers, gut microbiota profile, gut metabolites and cardiac remodeling in patients with Myocardial Infarction (MI)

Public title

The Effects of Lactobacillus rhamnosus in patients with Myocardial Infarction (MI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Myocardial Infarction and successful precancerous intervention (PCI) age range from 30-60 years body mass index (BMI) higher than 25 kg/m2 will be included in the study.

Exclusion criteria:

patient with chronic renal failure; hemodialysis previous myocardial infraction patients receiving immunosuppressive, anti-inflammatory and corticosteroid drugs; history of supplementation with pre/pro/symbiotic or antioxidants during previous two months will not be included in the study. with Being irritable bowel syndrome; Crohn's disease or ulcerative colitis Heart failure (functionclass III and IV), Heart valve diseases Subjects with diabetes

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants will be randomly allocated to intervention and placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout 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 Lactobacillus rhamnosus capsules and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company (Takgene Company).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City

Tabriz

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East Azarbaijan

Postal code

5166/15731

Approval date

2018-05-21, 1397/02/31

Ethics committee reference number

IR.TBZMED.REC.1397.184

Health conditions studied

1

Description of health condition studied

Myocardial Infarction (MI)

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Depression severity

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Beck Depression Inventory scale

2

Description

Physical activity level

Timepoint

Baseline and 12 weeks after intervention

Method of measurement
Via IPAQ questionnaire

3

Description
Quality of life
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Via MacNew questionnaire

4

Description
Lipid profile including HDL, LDL, TC and TG
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
HDL, TC and TG via enzymatic kit, LDL via friedewald equation

5

Description
Serum levels of Gut metabolites (TLR4, Zonulin and LPS)
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
TLR4, Zonulin and LPS measurements by ELISA

6

Description
Oxidative stress indices
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of serum levels of Total antioxidant capacity (TAC) and malondialdehyde (MDA) by spectrophotometry

7

Description
Serum level of Gut metabolite (TMAO)
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
TMAO level by MS / MS

8

Description
Inflammatory stress indices
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of inflammatory indices of hs-CRP, IL1B and IL-10 in serum by ELISA

9

Description
Level of ox-LDL
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of ox-LDL via ELISA kit

10

Description
Levels of TGF. Beta
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of TGF. Beta via ELISA kit

11

Description
Levels of NTpro BNP
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of NTpro BNP via ELISA kit

12

Description
Levels of MMP-9
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of NTpro BNP via ELISA kit

13

Description
Levels of Procolagen I
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of Procolagen I via ELISA kit

14

Description
Echocardiographic indices of cardiac remodeling including left ventricular end diastolic diameter (LVEDD), right ventricular end diastolic diameter (RVEDD), left ventricular end-diastolic volume (LVEDV), right ventricular end-diastolic volume (RVEDV) and Ejection Fraction (EF)
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
3-Dimentional Echocardiography

Secondary outcomes

1

Description
dietary inflammatory index (DII)
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
via Food Frequency Questionnaire

Intervention groups

1

Description
Intervention group: Patients in this group will receive probiotic capsule for 12 weeks. Probiotic capsule is a containing 1.6× 109 CFU of lactobacillus rhamnosus (a product by TacZist Co. and made in The Iran) and used once a day with lunch.
Category
Treatment - Drugs

2

Description
Control group:Patients in this group will receive maltodextrin capsules for 12 weeks which are same size and shape (product by TacZist Co. and made in The Iran) and used once a day with lunch.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Medical Research Training Center
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
Tabriz 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
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Full name of responsible person
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Person responsible for updating data

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Superviser, Professor, Associate professor

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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
1. Dr. Mohammad Alizadeh, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, +989141894102, mdalizadeh@tbzmed.ac.ir 2. Jalal Moludi, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, +989399516760, jmoludi@yahoo.com

What processes are involved for a request to access data/document
The applicator can send a request to the person responsible for the study by email and within 10 days the document will be sent to the requesting person.

Comments