

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

markers, gut microbiota profile and gut metabolite

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 1.6×10^9 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

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

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 infarction 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

Province
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 Procollagen I

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Measurement of Procollagen 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-Dimensional 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 1.6×10^9 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

Dr. Mohammad Alizadeh

Street address

Daneshgah street, Shahid Madani Medical Research Training Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Juyban

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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

Tabriz University of Medical Sciences

Full name of responsible person

Jalal Moludi

Position

Ph.D. candidate of nutrition sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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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