Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Sustainable Diet Combined with Time-Restricted Eating and Probiotic Supplementation on Cardiovascular Function among Patients with Chronic Heart Failure with reduced Ejection Fraction (HFrEF): A Randomized Clinical Trial Study

Protocol summary

Study aim

Preparation of LP299v Probiotic Supplements
Investigating of a sustainable diet in combination with TRE and probiotic supplements on cardiovascular function among patients with HFrEF

Design

A controlled clinical trial, parallel-group, single-blind, randomized, phase 3, among 90 HFrEF patients

Settings and conduct

This study is conducted in two phases, the probiotic capsule preparation phase and the clinical phase. The place of the study will be the cohort center of MUMS. After confirming the diagnosis of HFrEF by cardiologists, participants will be referred to the specialist for more detailed explanations if they participate in the project. After controlling inclusion criteria, the participants are assigned to one of the 3 study groups using stratified blocked randomization method and researcher and participants will be blinded. Also, unique codes generating by online website will be assigned on the medicinal container. As each person enters to study regarding to randomized consequences, medicinal container is assigned to person and no one (researcher and participants) know which participants will be in which intervention group. Medicine containers will also be opaque with closed lids and capsules will be the same in appearance, color, taste and smell.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of HFrEF Men and women with age range of 30-75 years, Complete the informed consent form Exclusion criteria: Using nutritional supplements, Not consuming more than 20% of the capsules, Unwillingness to continue cooperation in research

Intervention groups

Participants will be randomly divided into 3 groups: Dietary Advices + Probiotic Placebo: A Sustainable Diet with Time Restricted Eating + Probiotic Placebo: B Sustainable Diet with Time Restricted Eating + Probiotic Capsule: C

Main outcome variables

Echocardiography, biochemical and anthropometric indices

General information

Reason for update

We kindly request an update to the trial record due to modifications in the title and certain aspects of the methods used.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231225060520N1**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **prospective**

Last update: **2025-10-16, 1404/07/24**
Update count: **2**

Registration date

2024-01-23, 1402/11/03

Registrant information

Name

Pegah Rahbarinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 1524

Email address

pegah.rahbarinejad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-04-04, 1404/01/15
Expected recruitment end date
2026-02-04, 1404/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Sustainable Diet Combined with Time-Restricted Eating and Probiotic Supplementation on Cardiovascular Function among Patients with Chronic Heart Failure with reduced Ejection Fraction (HFrEF): A Randomized Clinical Trial Study

Public title
The Effect of Diet with probiotic on Cardiovascular Function
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of heart failure with echocardiogram showing systolic dysfunction with ejection fraction ≤ 40% based on New York Heart Association (NYHA) class II-IIID heart failure symptoms with ischemic or non-ischemic etiology Under standard treatment with drugs Men and women with age range of 30-75 years Willingness to participate in the study and complete the informed consent form
Exclusion criteria:
Use of nutritional supplements (oral or injectable, such as vitamins D, C, E, calcium, magnesium, potassium, multivitamin- mineral, omega 3) and herbal products with antioxidant and anti-inflammatory properties, probiotic or synbiotic supplements or products containing them during the study Not consuming more than 20% of the capsules Unwillingness to continue cooperation in research
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use stratified blocked randomization for random allocation. Body mass index (BMI) is considered as a classifier variable. By using the site www.sealdenvelope.com and the classifier variable (BMI) and selecting blocks of 6 on the site, a random sequence will be generated. The mentioned sequences are placed in opaque, numbered and sealed envelopes or SNOSE by the research associate. Upon entering each patient, after obtaining informed consent and checking the inclusion and non-inclusion and exclusion criteria, the first envelope is opened and the patient is assigned to one of the 3 relevant groups. In the same way, the randomization process will continue until the last patient. In order to apply concealment allocation in the random allocation process, unique codes will be used on medicine containers. So that the desired code is also generated by the online website. As each person enters the study based on the generated sequence, the medicine container in which the desired code is recorded is assigned to the person and therefore, before choosing the person, no one is aware of the type of treatment he/she will receive. Medicine containers are also non-transparent closed lids and capsules will be the same in terms of quantity, color, taste and smell.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is not blinded in terms of diet but will be blinded in terms of supplements. The probiotic supplement and its placebo will be produced by PARSILACT Company. All probiotic and its placebo supplements will provided by PARSILACT Company in prepacked pharmaceutical polyethylene bottle numbered for each patient according to the randomization sequence. The probiotic supplement and its placebo will be in the same form package. The researcher and patients will not be aware of the pharmaceutical polyethylene bottle's content until the end of the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Department of Nutrition, Faculty of Medicine, Ferdowsi University Campus, Azadi Square, Razavi Khorasan
City
Mashhad

Province
Razavi Khorasan
Postal code
9177948564
Approval date
2024-01-03, 1402/10/13
Ethics committee reference number
IR.MUMS.REC.1402.259

Health conditions studied

1

Description of health condition studied
Patients with Chronic Heart Failure with reduced Ejection Fraction (HFrEF)
ICD-10 code
I50.9
ICD-10 code description
Heart failure, unspecified

Primary outcomes

1

Description
N Terminal pro Natriuretic Peptide type B (NT-proBNP)
Timepoint
In the beginning of the study (before the start of the intervention) and 60 days after the intervention
Method of measurement
Kit for measuring N-terminal pro-natriuretic peptide type B in venous blood sample

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: Dietary advices + Probiotic placebo (without Lactobacillus plantarum 299v, twice daily for 60 days)
Category
Placebo

2

Description
Second Intervention group: Sustainable diet combined with time-restricted eating + Probiotic placebo (without Lactobacillus plantarum 299v, twice daily for 60 days)
Category
Treatment - Other

3

Description
Third Intervention group: Sustainable diet combined with time-restricted eating + Probiotic Capsule (Lactobacillus plantarum 299v with a dose of 14 billion CFU, twice daily for 60 days)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad University of Medical Sciences
Full name of responsible person
Pegah Rahbarinejad
Street address
Department of Nutrition, Faculty of Medicine, Ferdowsi University Campus, Azadi Square, Mashhad, Razavi Khorasan
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 7034
Email
pegah.rahbarinejad@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi Piadeh Gheibi
Street address
Research and Technology Vice Chancellor, Qurashi Building, next to Hoize Cinema, University St., Mashhad, Razavi Khorasan
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
Email
Tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Pegah Rahbarinejad

Position

Ph.D. Student

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Medicine, Ferdowsi University Campus, Azadi Square, Mashhad, Razavi Khorasan

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 21 8827 1524

Fax

Email

pegah.rahbarinejad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Pegah Rahbarinejad

Position

Ph.D. Student

Latest degree

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Phone

+98 21 8827 1524

Fax

Email

pegah.rahbarinejad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Pegah Rahbarinejad

Position

Ph.D. Student

Latest degree

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Fax

Email

pegah.rahbarinejad@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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