

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of probiotic yogurt and ordinary yogurt consumption on serum Pentraxin3, NT-proBNP, ApoB100, oxLDL, ADMA, LCAT activity, sCD163 to sTWEAK ration and Urea nitrogen in patients with chronic heart failure

Protocol summary

Study aim

Comparison of probiotic yogurt and ordinary yogurt consumption on serum Pentraxin 3, N-terminal prohormone of brain natriuretic peptide, Apo B100, oxidized low density lipoprotein, ADMA, lecithin Cholesterol acyl transferase activity, sCD163 to sTWEAK ration and urea nitrogen in patients with chronic heart failure

Design

the permuted block randomization will be used with quadruple blocks. According to the sample size of 90, 23 blocks will be produced using the online site (www.sealedenvelope.com). This study is in the third phase of clinical trial

Settings and conduct

The present study will be carried out as a double-blind randomized clinical trial in patients with chronic heart failure who referred to the Shahid Rajaei Cardiology Center. No changes in physical activity or diet are expected during the study.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Age range 30-70 years. 2. Having common symptoms of heart failure for at least 1 month. 3. Decreased LVEF (less than 40%). 4- Being in one of the NYHA classification steps 1-3 5- Desire to participate in the study and sign a written informed consent Non-inclusion criteria: 1- Cases of other diseases and chronic and acute liver disorders, diabetes, thyroid disorders, severe renal dysfunction, pulmonary diseases, inflammatory diseases and Known autoimmune, cancer, rheumatoid arthritis, acute infection. 2- taking any nutritional supplement during the past month. 3- smoking and narcotic drugs consumption. 4- Intolerance to lactose and allergy to dairy products. 5- taking corticosteroid in the last 4 weeks

Intervention groups

1. Intervention group: receive 300 grams of probiotic yogurt per day for 10 weeks. 2. Control group :receive 300 grams of ordinary yogurt per day for 10 weeks.

Main outcome variables

Pentraxin 3 and oxLDL

General information

Reason for update

Adding a new factor (Urea nitrogen) and removing deleted factors (ApoA1 and PON1 activity and lipid profile)

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N48**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **prospective**

Last update: **2019-11-05, 1398/08/14**

Update count: **2**

Registration date

2018-03-12, 1396/12/21

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of probiotic yogurt and ordinary yogurt consumption on serum Pentraxin3, NT-proBNP, ApoB100, oxLDL, ADMA, LCAT activity, sCD163 to sTWEAK ration and Urea nitrogen in patients with chronic heart failure

Public title

Comparison of probiotic yogurt and ordinary yogurt consumption in patients with chronic heart failure.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 30 to 70 years Having common symptoms of heart failure for at least 1 month decreased LVEF ($\leq 40\%$) Being in one of the NYHA classification steps 1-3 Desire to participate in the study and sign a written informed consent

Exclusion criteria:

suffering or having chronic and acute liver (hepatitis B, C, etc.) Diseases and other, diabetes, thyroid disorders, severe renal dysfunction (creatinine more than 300 millimol/liter), pulmonary disease, known inflammatory and autoimmune diseases, Cancer, Rheumatoid Arthritis, Acute Infection taking any nutritional supplement during the past month smoking and using narcotic drugs Lactose intolerance and allergy to dairy products taking Corticosteroid drug in the last 4 weeks taking antibiotics over the past 3 months History of Gastrointestinal Surgery Taking anti-inflammatory drugs other than low dose of aspirin (one per day) Having an artificial heart valve History of rheumatic heart disease Pregnancy and lactation taking insulin body mass index more than 30 Kilogram/meter²

AgeFrom **30 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

For randomization, the permuted block randomization

will be used with quadruple blocks. According to the sample size of 90 , 23 blocks will be produced using the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to apply concealment in the randomization process, unique codes will be used on yogurt containers, the code being generated by the software. By entering each individual into a study based on the produced sequence , the yogurt container in which the code is registered will be assigned to the individual. During the research, the random list is provided to the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups.

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

Hemat Express way, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.IUMS.REC 1396.9511468002

Health conditions studied**1****Description of health condition studied**

Chronic heart failure

ICD-10 code

I50.9

ICD-10 code description

Cardiac, heart or myocardial failure NOS

Primary outcomes

1

Description

Serum pentraxin3

Timepoint

Measurement of serum pentraxin3 at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

ELISA kit

2

Description

Serum oxidized low density lipoprotein

Timepoint

Measurement of serum oxidized low density lipoprotein at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Serum N-terminal prohormone of brain natriuretic peptide

Timepoint

Measurement of Serum N-terminal prohormone of brain natriuretic peptide at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

ELISA kit

2

Description

Serum Apolipoprotein B100

Timepoint

Measurement of Serum Apolipoprotein B100 at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

Immunoturbidimetry

3

Description

Serum Asymmetric dimethylarginine

Timepoint

Measurement of Serum Asymmetric dimethylarginine at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

ELISA kit

4

Description

Serum lecithin Cholesterol acyl transferase activity

Timepoint

Measurement of Serum lecithin Cholesterol acyl transferase activity at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

ELISA kit

5

Description

sCD163 to sTWEAK ration

Timepoint

Measurement of Serum sCD163 to sTWEAK ration at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

ELISA kit

6

Description

Serum urea nitrogen

Timepoint

Measurement of Serum urea nitrogen at the beginning of the study (before the intervention) and the end of the study (10 weeks after starting probiotic yogurt consumption).

Method of measurement

Enzymatic colorimetric

Intervention groups

1

Description

Intervention group: Consumption of Probiotic yogurt (300 gr/day for 10 weeks). Probiotic yogurt is prepared in the form of low-fat yogurt (1.5% fat) containing 10⁹ cfu /gr of Lactobacillus acidophilus La5 and lactobacillus bifidobacterium Bb12 by Pak dairy factory.

Category

Placebo

2

Description

Control group: Consumption of ordinary yogurt (300 gr/day for 10 weeks) that is prepared by Pak dairy factory.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid rajaie cardiovascular, medical and research center

Full name of responsible person

Dr Nasim naderi

Street address

Shahid Rajaei Cardiovascular Medical and Research Center, Niayesh Intersection, Next to Mellat Park, Valiasr Ave, Tehran Iran

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Naderi.nasim@gmail.com

Web page address

<http://www.rhc.ac.ir>

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.Farzad Shidfar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr.Seyed Kazem Malakooti

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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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr.Farzad Shidfar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Behnaz Pourrajab

Position

Ms.c student in nutrition science

Latest degree

Bachelor

Other areas of specialty/work

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Behnazpourrajab@gmail.com

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 part of the data will be shared, such as
information about primary outcomes and Etc.

When the data will become available and for how long

The access period will be 6 months after publication of
the results.

To whom data/document is available

The obtained data from current study will be available
only for researchers working in academic and scientific
institutions.

Under which criteria data/document could be used

Six months after the publication of the papers from this
study, the data obtained will be available to the applicant
researchers for further analysis.

From where data/document is obtainable

Applicants can be contacted with correspond author by
e-mail or postal address to receive the requested data.
Postal address: Nutrition department, School of health,
Iran University of Medical Sciences, Hemmat
expressway, Tehran Phon number:0098 21 8862 2755 E-
mail: Farzadshidfar@yahoo.com

What processes are involved for a request to access data/document

Applicants will be able to access the obtained data from
current study by sending an email to the corresponding
author, after a maximum of one week.

Comments