

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of synbiotic consumption on serum NTproBNP, hsCRP and blood pressure in patients with heart failure

Protocol summary

Study aim

The effect of synbiotic consumption on serum NTproBNP, hsCRP and blood pressure in patients with heart failure

Design

Randomization is done in the form of random blocks of volume 4 and the random list is compiled by statistical software. Randomization and blinding of the study are performed to maintain concealment. 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 Rajaee Cardiology Center. No changes in physical activity or diet are expected during the study.

Participants/Inclusion and exclusion criteria

inclusion criteria; 1- Age range from 30 to 70 years old 2- Patients with systolic heart failure (LVEF less than 40%) 3- Being in one of the NYHA classification steps 1-3 4- Willingness to participate in the study and sign informed written consent 5- Lack of other diseases including chronic and acute liver disorders (hepatitis B, C, etc.), diabetes, thyroid disorders, severe renal dysfunction (creatinine less than 300 mmol/l), pulmonary diseases, inflammatory and autoimmune diseases, Cancer, acute infection 6- Not using any nutritional supplements for the past two months. 7- No substance abuse and smoking 8- Not taking Corticosteroids in the past 4 weeks 9- Not taking antibiotics in the past 3 months 10- BMI less than 30. Non-inclusion criteria; 1- Not willing to continue cooperation 2- Use of less than 80% of supplements given to the patient during the study period 3- Changes in the type and dose of drug which is using by the patient.

Intervention groups

1. Intervention group = receive one capsule of lactocare synbiotic per day for 10 weeks 2. Control group = receive one placebo capsule per day for 10 weeks

Main outcome variables

NtproBNP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N52**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-17, 1398/07/25

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic consumption on serum NTproBNP, hsCRP and blood pressure in patients with heart failure

Public title

The effect of synbiotic use on heart failure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range from 30 to 70 years Patients with systolic heart failure (LVEF <40%) approved by a cardiologist and receiving at least 3 months of standard heart failure treatment , Medications have reached the maximum tolerated dose and their medication dose will remain constant throughout the study. class 1,2 and 3 of NYHA classification Willingness to participate in the study and sign informed written consent Lack of other diseases including chronic and acute liver disorders (hepatitis B, C, etc.), diabetes, thyroid disorders, severe renal dysfunction (300 mmol /l $\leq$ creatinine), pulmonary diseases, inflammatory and autoimmune diseases, Cancer, acute infection Not using any nutritional supplements for the past two months. No substance abuse and smoking Not taking Corticosteroids in the past 4 weeks Failure to receive antibiotics in the past 3 months No history of gastrointestinal surgery No anti-inflammatory drugs except low-dose aspirin (one 80 mg daily) No artificial heart valve No history of rheumatic heart disease Not being pregnant and breastfeeding Lack of insulin BMI< 30

Exclusion criteria:

Not willing to continue cooperation use of less than 80% of supplements given to the patient during the study period Acceptance rate = The number of capsules given to the patient - the Number of capsules not used / The number of capsules given to the patient other disease such as metabolic diseases,Cancer and inflammatory diseases during the study that Need special treatment or antibiotic use. Changes in the type and dose of drug which is using by the patient .

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in the form of random blocks of volume 4 and the random list is compiled by statistical software. Randomization and blinding of the study are performed to maintain concealment. In case of deviation from the protocol, the data is analyzed by the Intention to Treat (ITT) method , so that statistical analysis of

clinical trials of data obtained from participants at the end will be performed using randomization that was randomized at the beginning of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study subjects and researchers will be blinded to the intervention. Synbiotics and placebo capsules are similar in appearance, odor, weight and packaging and only the code on the package (A or B) is different.

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

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Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-09-27, 1398/07/05

Ethics committee reference number

IR.IUMS.REC.1398.675

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

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes**1****Description**

NT-probnp

Timepoint

Before and after intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

sphygmomanometer

2

Description

high-sensitivity C-reactive protein (hs-CRP)

Timepoint

Before intervention and 10 weeks after the start of intervention

Method of measurement

immunoturbidimetric tests

Intervention groups

1

Description

Intervention group: Patients will be given 1 capsule of lactocare synbiotic daily for 10 weeks. Lactocare Synbiotic Capsules are manufactured by Zist Takhmir Company. Lactocare is an oral capsule containing high levels of beneficial bacteria (Lactobacilli, Bifidobacteria and Streptococcus) with prebiotic fructo-oligosaccharide (contributing to growth and probiotic activity).

Category

Treatment - Drugs

2

Description

Control group: Patients consume one placebo capsule daily for 3 weeks. Placebo capsules are produced by Zist Takhmir company.

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Seyed abbas Motevalian

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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

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

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Person responsible for updating data

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Full name of responsible person

shakiba shoaee matin

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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

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

Some of the data will be shared, such as information
about the main consequences 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

