Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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 3months 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 = recieve one capsule of lactocare synbiotic per day for 10 weeks 2. Control group = recieve one plasebo 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

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Farzad Shidfar

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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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 ≤ 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

City
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 eill 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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Naderi.nasim@gmail.com
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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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Iran University of Medical Science, Hemmat expressway
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Phone
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Email
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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
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Person responsible for updating data

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Position
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Bachelor
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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