Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of synbiotic consumption on serum paraoxonase 1(PON1), Soluble CD163/Soluble TNF-like weak inducer of apoptosis(sCD163/sTWEAK) and lipid profile in patients with chronic heart failure

Protocol summary

Study aim
The effect of synbiotic consumption on serum paraoxonase 1(PON1), Soluble CD163/Soluble TNF-like weak inducer of apoptosis(sCD163/sTWEAK) and lipid profile in patients with chronic 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
This study will be a 10-weeks 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.

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
sCD163/sTWEAK, paraoxonase1, lipid profile

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091114002709N55**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date
2020-11-04, 1399/08/14

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
2020-08-13, 1399/05/23

Expected recruitment end date
2021-02-11, 1399/11/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of synbiotic consumption on serum paraoxonase 1(PON1), Soluble CD163/Soluble TNF-like weak inducer of apoptosis(sCD163/sTWEAK) and lipid profile in patients with chronic 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 yearsPatients 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 classificationWillingness to participate in the study and sign informed written consentLack 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 infectionNot using any nutritional supplements for the past two months.No substance abuse and smokingNot taking Corticosteroids in the past 4 weeksFailure to receive antibiotics in the past 3 monthsNo history of gastrointestinal surgeryNo anti-inflammatory drugs except low-dose aspirin (one 80 mg daily)No artificial heart valveNo history of rheumatic heart diseaseNot being pregnant and breastfeedingLack of insulin BMI< 30
Exclusion criteria:
Not willing to continue cooperationuse 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 patientother 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
- Care provider
- Investigator
- Outcome assessor
- Data analyser

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
2020-10-26, 1399/08/05
Ethics committee reference number
IR.IUMS.REC.1399.707

2

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
2019-05-03, 1398/02/13

Ethics committee reference number
IR.IUMS.REC.1398.1330

3

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
2020-03-03, 1398/12/13

Ethics committee reference number
IR.IUMS.REC.1398.1329

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
sCD163 to sTWEAK ration

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
ELISA kit

Secondary outcomes

1

Description
paraoxonase 1

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
ELISA kit

2

Description
Triglyceride

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
colorimetri

3

Description
Total cholestrol

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
colorimetri

4

Description
LDL-c

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
colorimetri

5

Description
HDL-C

Timepoint
Before intervention and 10 weeks after the start of intervention

Method of measurement
colorimetri

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
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 8862 2755
Fax
+98 21 2204 2026
Email
Naderi.nasim@gmail.com
Web page address
http://www.rhc.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr.Seyed abbas Motevalian
Street address
Iran University of Medical Science, Hemmat expressway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
amotevalian@iums.ac.ir
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
Street address
School of health, Iran university of medical science, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
Shidfar.f@iums.ac.ir

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
Street address
School of health, Iran university of medical science,

Shahid Hemmat highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8862 2755

Fax
+98 21 8862 2533

Email
Shidfar.f@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
shakiba shoaee matin

Position
Ms.c student in nutrition science

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
School of health, Iran university of medical science, Shahid Hemmat highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 11 5522 3547

Email
shakiba.matin@yahoo.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
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