

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of L-Arginine supplementation on the levels of glucose, N-Terminal pro Brain Natriuretic Peptide (NT pro-BNP), lipids, blood pressure, ejection fraction, quality of life and rehabilitation in patients with congestive heart failure.

Protocol summary

Study aim

The effect of L-Arginine supplementation on the levels of glucose, N-Terminal pro Brain Natriuretic Peptide (NT pro-BNP), lipids, blood pressure, ejection fraction, quality of life and rehabilitation in patients with congestive heart failure.

Design

A randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct

double-blind randomized clinical trial on 44 subjects (35 to 65 years) with ischemic heart failure who are eligible for inclusion in the Heart Center Hospital of Tehran. Responsible for project and the patient are unaware of the intervention and placebo groups. Patients were randomly assigned to one of the groups.

Participants/Inclusion and exclusion criteria

Inclusion 1- Age 35-65 years 2- Diagnosis of ischemic heart failure 3- Ejection fraction less than 40% 4- Cardiac functional level of 2 or 3 based on the classification of the New York heart association Exclusion 1- Any kidney, liver or inflammatory bowel diseases, malignancies, thyroid disorders 2- Pregnancy and lactation 3- Taking any dietary supplement including L-arginine within the past 2 months prior to the initiation of the study 4- History of angina pectoris, myocardial infarction or stroke, untreated arrhythmias 5- Taking medication including glucocorticoids, anti-arrhythmic or chemotherapy agents, NSAIDs, diltiazem, verapamil, thiazolidinedione 6- Unable to perform 6 minute walking test

Intervention groups

Chronic ischemic heart failure patients with reduced ejection fraction who have the study's inclusion criteria. Randomly divided into two groups: L-Arginine-supplementation or placebo

Main outcome variables

Serum glucose; Serum lipids; NT pro bnp; ejection fraction; Systolic and diastolic blood pressure; 6-Minute Walking Test; Minnesota's quality of life questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170202032367N4**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **retrospective**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

Hossien Imani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

h-imani@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of L-Arginine supplementation on the levels of glucose, N-Terminal pro Brain Natriuretic Peptide (NT pro-BNP), lipids, blood pressure, ejection fraction, quality of life and rehabilitation in patients with congestive heart failure.

Public title

The effect of L-arginine supplementation in patients with congestive heart failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 35-60 years Diagnosis of ischemic heart failure Ejection fraction less than 40% (based on echocardiography test) Cardiac functional level of 2 or 3 based on the classification of the New York heart association

Exclusion criteria:

Kidney, liver or inflammatory bowel diseases, malignancies, thyroid disorders Pregnancy and lactation Taking any dietary supplement including L-arginine within the past 2 months prior to the initiation of the study History of angina pectoris, myocardial infarction or stroke, untreated arrhythmias Taking medications including glucocorticoids, antiarrhythmic or chemotherapy agents, NSAIDs, diltiazem, verapamil, thiazolidinedione Unable to perform 6 minute walking test

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Regarding to the diabetic status, patients were randomly classified into two groups to receive either L-arginine-supplement or placebo. Stratified Blocked Randomization method was used to randomly assign patients to study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blinding the allocation, similar boxes of L-arginine or placebo were labeled by an independent person as A or B. Patients, the main researcher and the cardiologist were blind in this study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee Tehran University of Medical Sciences

Street address

No 605 room, Sixth floor, Central building of Tehran University of Medical Sciences, Keshavarz boulevard, Ghods street, Tehran

City

Tehran

Province

Tehran

Postal code

141556117

Approval date

2018-09-06, 1397/06/15

Ethics committee reference number

IR.TUMS.VCR.REC.1397.345

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

congestive heart failure

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

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

Serum Triglyceride

Timepoint

Before and after of intervention

Method of measurement

Enzymatic method with auto analyzer- mg/dl

2

Description

Serum Total cholestrol

Timepoint

Before and after of intervention

Method of measurement

Enzymatic method with auto analyzer- mg/dl

3

Description

Serum Low Density Lipoprotein Cholestrol (LDL-C)

Timepoint

Before and after of intervention

Method of measurement

Calculate according to fridval formula - mg/dl

4

Description

Serum High Density Lipoprotein Cholestrol (HDL-C

Timepoint

Before and after of intervention

Method of measurement

Enzymatic method with autoanalyzer- mg/dl

5

Description

n-terminal pro brain natriuretic peptide

Timepoint

Before and after of intervention

Method of measurement

ELISA

6

Description

Fasting Blood Sugar

Timepoint

Before and after of intervention

Method of measurement

Glucose oxidase

7

Description

The Minnesota Quality of Life Questionnaire

Timepoint

Before and after of intervention

Method of measurement

questionnaire

8

Description

Left ventricular ejection fraction

Timepoint

Before and after of intervention

Method of measurement

Left ventricular EF percentage for echocardiography

9

Description

Systolic blood pressure

Timepoint

Before and after of intervention

Method of measurement

Digital sphygmomanometer

10

Description

Diastolic blood pressure

Timepoint

Before and after of intervention

Method of measurement

Digital sphygmomanometer

11

Description

Distance traveled on 6 minute walk test

Timepoint

Before and after of intervention

Method of measurement

Distance walked in 6 minutes (standard walking route)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: L-Arginine supplement (3 g / day) after breakfast, lunch, dinner for 10 weeks.take it orally and this supplement produced by Karen company.

Category

Treatment - Other

2

Description

Placebo group: Oral placebo (including maltodextrin) 3 times daily after breakfast, lunch, dinner for 10 weeks orally. Placebo is quite similar in appearance, color, odor and taste. Produced by Karen.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Mahnaz Aalmani

Street address

North karegar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Tehran 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

Tehran University of Medical Sciences
Full name of responsible person
Mahnaz Salmani
Position
Master of Science Student
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Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The patient's anthropometric and clinical information is confidential

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The original outcome can be shared

When the data will become available and for how long

Get started since 1398

To whom data/document is available

Responsible for designing Dr. Imani and Dr. Navid. Lady mahnaz barber

Under which criteria data/document could be used

The names of the design authorities may be used

From where data/document is obtainable

Refer to Dr. Imani

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

Email Dr. Imani

Comments