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)

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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
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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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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
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
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Mahnaz Salmani
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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