Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Clinical trial of the effect of selenium supplementation on metabolic profiles in patients with congestive heart failure.

Protocol summary

Study aim
Objective: The aim of this study is to determine the effect of selenium supplementation on metabolic profiles in patients with Congestive Heart Failure (CHF).

Design
Clinical trial with control group, parallel groups, double blind, randomized, 60 samples, phase 3

Settings and conduct
Among CHF patients referred to Cardiology Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals aged 45-85 years diagnosed with CHF will be included in this study. Exclusion criteria: Exclusion Criteria: Those consuming Selenium supplements within the past 3 months, having an acute myocardial infarction within the past 3 months, having cardiac surgery within the past 3 months and significant renal or hepatic failure.

Intervention groups
Intervention group: selenium tablet (Webber Naturals, Mississauga, Canada, 200 µg, daily, for 12 weeks orally. Control group: placebo tablet (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.

Main outcome variables
Markers of insulin metabolism (primary outcomes) and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcome)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017053033941N2**
Registration date: **2017-07-04, 1396/04/13**
Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date
2017-07-04, 1396/04/13

Registrant information

Name
Mohammadreza Sharif

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2017-06-01, 1396/03/11

Expected recruitment end date
2017-06-15, 1396/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of selenium supplementation on metabolic profiles in patients with congestive heart failure.

Public title

Effect of supplementation in treatment of Congestive Heart Failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria: Subjects diagnosed with CHF Individuals aged 45-85 years;

Exclusion criteria:

Those consuming Selenium supplements within the past 3 months, having an acute myocardial infarction within the past 3 months, having cardiac surgery within the past 3 months significant renal or hepatic failure

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of Stat Trek software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IR.Kaums.REC.1396.41

Health conditions studied

1

Description of health condition studied

Congestive Heart Failure

ICD-10 code

I50.0

ICD-10 code description

Congestive Heart Failure

Primary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of

intervention
Method of measurement
Enzymatic kit

3

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

8

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Systolic blood pressure
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Manometer

10

Description
Diastolic blood pressure
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Manometer

Intervention groups

1

Description
Intervention group: selenium tablet (Webber Naturals, Mississauga, Canada, 200 µg, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: placebo tablet (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology outpatient clinic
Full name of responsible person
Zatollah Asemi
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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asemi_z@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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