

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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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 \geq 25 kg/m²) and age (<65 and \geq 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

Isfahan

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

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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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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

Ph.D.

Other areas of specialty/work

Nutrition

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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