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
Vahidreza Ostadmohammadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5546 3378
Email address
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 kg/m2 and ≥25 kg/m2) and age (<65 y 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**
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

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
Cardiology outpatient clinic

Full name of responsible person
Zatollah Asemi

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfahan

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8715988141

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+98 31 5546 3378

Email
asemi_z@kaums.ac.ir
## Sponsors / Funding sources

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
<th>Province</th>
<th>Postal code</th>
<th>Phone</th>
<th>Email</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Vice chancellor for research, Kashan University of Medical Sciences</td>
<td>Gholamali Hamidi</td>
<td>Ghotbe Ravandi Boulevard, Kashan</td>
<td>Kashan</td>
<td>Isfahan</td>
<td>8715988141</td>
<td>+98 31 5546 3378</td>
<td><a href="mailto:asemi_z@kaums.ac.ir">asemi_z@kaums.ac.ir</a></td>
</tr>
</tbody>
</table>

### Grant name
- **Grant code / Reference number**: 8715988141
- **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
- **Country of origin**: empty
- **Type of organization providing the funding**: Academic

### Person responsible for general inquiries

<table>
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<tr>
<th>Contact</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Position</th>
<th>Latest degree</th>
<th>Other areas of specialty/work</th>
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<td>Full name of responsible person</td>
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### Person responsible for scientific inquiries

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### Person responsible for updating data

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</thead>
</table>

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8715988141
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asemi_z@kaums.ac.ir
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