Effects of zinc supplementation on nitric oxide and biomarkers of oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim
The aim of this study is to determine the effects of zinc supplementation on nitric oxide and biomarkers of oxidative stress in women with polycystic ovary syndrome (PCOS).

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct
Population and sample size: 48 women with PCOS eligible and referred to Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Hyperprolactinemia, thyroid disorders, liver or kidney diseases, pregnancy and lactation, the use of medications such as insulin sensitizers, insulin, and diuretics, subjects following a special diet or consuming drugs with an effect on hormonal profile like oral contraceptives (OCP), steroid hormones, or any other drugs probably to affect ovarian action in the last 3 months, T2DM

Intervention groups
Intervention: Patients will be assigned to receive either 50 mg zinc supplement (intervention group: n=24) or placebo (control group: n=24). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure nitric oxide and biomarkers of oxidative stress. Start and End Date of Intervention: 8 weeks

Main outcome variables
Outcomes: Free testosterone, dehydroepiandrosterone (DHEA), alopecia and hirsutism (primary outcome), and other hormonal profiles, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at the study baseline and end-of-trial.

General information
Reason for update
Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym
IRCT registration information
IRCT registration number: IRCT201407115623N24
Registration date: 2014-11-09, 1393/08/18
Registration timing: retrospective

Last update: 2019-11-01, 1398/08/10
Update count: 1

Registration date 2014-11-09, 1393/08/18

Registrant information
Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status
Recruitment complete

Funding source
Arak University of Medical Sciences

Expected recruitment start date
2014-05-22, 1393/03/01

Expected recruitment end date
2014-06-04, 1393/03/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of zinc supplementation on nitric oxide and biomarkers of oxidative stress in women with polycystic
Public title
Effect of supplementation in treatment of polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18-40 years Patients with PCOS according to Rotterdam criteria

Exclusion criteria:
Hyperprolactinemia Thyroid disorders Liver or kidney diseases Pregnancy and lactation The use of medications such as insulin sensitizers, insulin, and diuretics. Subjects following a special diet or consuming drugs with an effect on hormonal profile like oral contraceptives (OCP), steroid hormones, or any other drugs probably to affect ovarian action in the last 3 months T2DM

Age
From 18 years old to 40 years old

Gender
Female

Phase
3

Groups that have been masked
- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: 48

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take zinc supplementation (n=24) or placebo (n=24). Randomization will be done by the use of computer-generated random numbers.

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
Arak University of Medical Sciences

Street address
Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City
Arak

Province
Markazi

Postal code
3814113634

Approval date
2014-05-21, 1393/02/31

Ethics committee reference number
4-164-93

Health conditions studied

1
Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1
Description
Free testosterone

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa kit

2
Description
Dehydroepiandrosterone (DHEA)

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa kit

3
Description
Hirsutism

Timepoint
Baseline and End-of-trial

Method of measurement
Clinical observation

4
Description
Alopecia

Timepoint
Baseline and End-of-trial

Method of measurement
Clinical observation
### Secondary outcomes

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>17-OH progesterone</td>
<td>Baseline and End-of-trial</td>
<td>Elisa</td>
</tr>
<tr>
<td>Prolactin</td>
<td>Baseline and End-of-trial</td>
<td>Elisa</td>
</tr>
<tr>
<td>FSH</td>
<td>Baseline and End-of-trial</td>
<td>Elisa</td>
</tr>
<tr>
<td>LH</td>
<td>Baseline and End-of-trial</td>
<td>Elisa</td>
</tr>
<tr>
<td>Hs-CRP</td>
<td>Baseline and End-of-trial</td>
<td>Elisa</td>
</tr>
<tr>
<td>Total antioxidant</td>
<td>Baseline and End-of-trial</td>
<td>Spectrophotometry</td>
</tr>
<tr>
<td>Glutathione</td>
<td>Baseline and End-of-trial</td>
<td>Spectrophotometry</td>
</tr>
<tr>
<td>Nitric oxide</td>
<td>Baseline and End-of-trial</td>
<td>Spectrophotometry</td>
</tr>
<tr>
<td>Malondialdehyde</td>
<td>Baseline and End-of-trial</td>
<td>Spectrophotometry</td>
</tr>
</tbody>
</table>

### Intervention groups

<table>
<thead>
<tr>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention group: Zinc tablet, 50 mg, daily, for 8 weeks orally.</td>
<td>Treatment - Drugs</td>
</tr>
<tr>
<td>Control group: Placebo tablet, daily, for 8 weeks orally.</td>
<td>Treatment - Drugs</td>
</tr>
</tbody>
</table>

### Recruitment centers

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kosar outpatient Clinic</td>
<td></td>
</tr>
</tbody>
</table>

| Full name of responsible person | Mehri Jamilian |
| Street address | Emam Khomeyni Avenue, Arak |
| City | Arak |
| Province | Markazi |
| Postal code | 3848176941 |
| Phone | +98 84 3223 3823 |
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### Sponsors / Funding sources
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
Arak 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 Science

Full name of responsible person
Zatollah Asemi

Position
Nutrition PhD

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Associate professor

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