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
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Kashan University of Medical Sciences
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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 ovary syndrome
Effect of supplementation in treatment of polycystic ovary syndrome

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

Age
- From 18 years old to 40 years old

Gender
- Female

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
- 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

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

1
Description
17-OH progesterone
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

2
Description
Prolactin
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

3
Description
FSH
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

4
Description
LH
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

5
Description
Hs-CRP
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

6
Description
Total antioxidant
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

7
Description
Glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

8
Description
Nitric oxide
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

9
Description
Malondialdehyde
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

Intervention groups

1
Description
Intervention group: Zinc tablet, 50 mg, daily, for 8 weeks orally.
Category
Treatment - Drugs

2
Description
Control group: Placebo tablet, daily, for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Kosar outpatient Clinic
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
Email
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Sponsors / Funding sources
Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutrition PhD
Latest degree
Ph.D.
Other areas of specialty/work
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81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Province
Isfahan
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81151-87159
Phone
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asemi_z@kaums.ac
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