Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effects of chromium supplementation on hormonal status in women with polycystic ovary syndrome

Protocol summary

Study aim
Objective: the aim of this study is to determine the effects of chromium supplementation on hormonal status 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: 60 women with PCOS eligible and referred to Endocrinology and Gynecology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18-40 years old diagnosed with PCOS. Exclusion criteria: Individuals with elevated levels of prolactin, thyroid disorder, endocrine diseases including diabetes or impaired glucose tolerance, gastrointestinal problems.

Intervention groups
Intervention group: Chromium tablet, 200 µg, daily, for 8 weeks orally. Control group: Placebo tablet, daily, for 8 weeks orally.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201506105623N44**
Registration date: **2015-06-27, 1394/04/06**
Registration timing: **registered_while_recruiting**
Last update: **2019-10-01, 1398/07/09**
Update count: **1**

Registration date
2015-06-27, 1394/04/06

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2015-06-22, 1394/04/01

Expected recruitment end date
2015-07-02, 1394/04/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of chromium supplementation on hormonal status in women with polycystic ovary syndrome

Public title
Effect of supplementation in treatment of polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18-40 years old diagnosed with PCOS

Exclusion criteria:

Individuals with elevated levels of prolactin Thyroid disorder Endocrine diseases including diabetes or impaired glucose tolerance Gastrointestinal problems

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline, after balanced blocked randomisation, subjects will be allocated into two groups to take supplements (n = 30) or placebo (n = 30). 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

Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

1771844351

Approval date

2015-06-02, 1394/03/12

Ethics committee reference number

IR.Kaums.REC.1394.33

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Free testosterone

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Prolactin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

2

Description

FSH

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

3

Description

LH

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

4

Description

Hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

5

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

6

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

7

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

8

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

9

Description
DHEA
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

Intervention groups

1

Description
Intervention group: Chromium tablet, 200 µg, daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily, for 8 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and gynecology Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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1771844351
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
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81151-87159
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+98 31 5554 2999
Email
research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Position
Nutrition PhD

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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