

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of the therapeutic effect of chromium supplementation with doses of 400 and 600 micrograms on body mass index, insulin sensitivity and depression, anxiety and stress in polycystic ovary syndrome

Protocol summary

Study aim

Determination of the therapeutic effect of chromium supplementation with doses of 400 and 600 micrograms on body mass index, insulin sensitivity and depression, anxiety and stress in polycystic ovary syndrome

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 120 patients. Random allocation was used for randomization.

Settings and conduct

This study will be performed in the gynecology clinic of Shahrekord University of Medical Sciences on women with polycystic ovary syndrome who are eligible for the study. Patients who have consciously signed a consent form to participate in the project will be randomly (by block method) into three groups. Intervention group 1: Chromium supplement 400 micrograms daily orally for two months. Intervention group 2: Chromium supplement 600 micrograms per day orally for two months, intervention group 3: oral placebo tablets once daily for two months. participants and statistical expert are unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCO Exclusion criteria: take chromium picolinate supplement regularlyHydroxy; progesterone above 2

Intervention groups

Intervention group 1: Chromium supplement 400 micrograms daily orally for two months Intervention group 2: Chromium supplement 600 micrograms one orally daily for two months Intervention group 3: Oral placebo tablets once daily for two months

Main outcome variables

BMI,insulin sensitivity , depression, anxiety , stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210515051298N1**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Zahra Bakhtiari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

bakhtiari@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the therapeutic effect of chromium supplementation with doses of 400 and 600 micrograms on body mass index, insulin sensitivity and depression, anxiety and stress in polycystic ovary syndrome

Public title

Effect of the therapeutic effect of chromium supplementation with doses of 400 and 600 micrograms on body mass index

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction of patients aged 16 to 40 years Polycystic Ovary Syndrome

Exclusion criteria:

Take chromium picolinate supplement regularlyHydroxy Progesterone above 2

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher will use a table of random numbers to select the sample. It randomly starts from a point in the table in the direction of a row or column. The selection of the point can be done by closing the eyes and placing a finger or the tip of a pen on the table. The movement does not differ in the direction of the row or column, and this is up to the researcher. But according to the type of code digits (one digit, two digits, three digits, etc.) he must select the same number of digits in the row or column direction. It then controls the route numbers. He will inevitably encounter two types of numbers, one of which is smaller than the number of the population of the study and the other of which is larger than the number of the population. He should only consider and select smaller numbers. The selected number is in fact the individual code of the community that is selected as a sample. This should be continued until a small number can be selected based on the number of sample people. After completing the sample size, the sampling work is completed. For this study, 80 sealed envelopes will be numbered 1-120 according to the randomization list. Group allocation will be kept separate until the study is completed. with 40 envelopes allocated to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind ,after completing the study and collecting the results, the relevant codes will be

provided to each patient team and the method of performing the double-blind nature of the study was such that neither the patient nor the researcher were aware of patient allocation. They were similarly packaged to avoid identification

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology, Shahrekord University of Medical Sciences,Kashani Blvd, Shahrekord,Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.SKUMS.REC.1400.039

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Body mass index

Timepoint

Two months after the start of the intervention

Method of measurement

Questionnaire

2

Description

Insulin sensitivity

Timepoint

Two months after the start of the intervention

Method of measurement

Questionnaire

3

Description

Depression

Timepoint

Two months after the start of the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Chromium supplement 400 micrograms of CENTURY company daily orally for two months

Category

Treatment - Drugs

2

Description

Intervention group 2: Chromium supplement 600 micrograms daily of CENTURY company orally for two months

Category

Treatment - Drugs

3

Description

Control group: Oral placebo tablets once daily for two months of Darupakhsh Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Belgheyse Mohammadi

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran

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mohammadi.b@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Vice Chancellor of Research and Technology, Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord, Iran

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Belghese Mohammadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Belghese Mohammadi

Position

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

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