

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of Chromium Picolinate supplementation on weight, fat mass and Leptin serum in obese and overweight people

Protocol summary

Summary

This study is clinical trial. Obese and overweight individuals who live in Yazd participate in this study. Inclusion criteria: Body mass index (BMI) over 25 Kg / m²; men and women 20 to 50 years; without diabetes, CVD diseases; didn't heart surgery; lack of menopause; non smoking status; inactive (based on questionnaires) and Willing to participate in study. Exclusion criteria: don't use more than 20% drug that they have; unwillingness to do exercise; specific disease during study; smoking during study; menopause. They are assigned randomly to two groups (50 persons); intervention group consume 200 mcg Chromium Picolinate daily besides do 30 minutes exercise daily and control group just do exercise 30 minutes like intervention group. Every 14 days they receive their supplement. Measure BMI (Body Mass Composition) by Seca and tape meter, Fat Mass percent by Bc-418m1, TANITA, Japan instrument and serum Leptin by ELISA kit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012210826N6**
Registration date: **2014-01-29, 1392/11/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-29, 1392/11/09

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

azadnajarzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Science-
International branch

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2013-08-11, 1392/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Chromium Picolinate supplementation on weight, fat mass and Leptin serum in obese and overweight people

Public title

Chromium Picolinate and Obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Body mass index (BMI) over 25 Kg / m²; men and women aged 20 to 50 years old; without diabetes, CVD; didn't heart surgery; lack of menopause; non smoking status; inactive (based on questionnaires) and willing to participate in study. Exclusion criteria: don't use more than 20% drug that they have; unwillingness to do exercise; specific disease during study; smoking during study; menopause.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Sadoughi University of Medical Science

Street address

International campus of Shahid Sadoughi University
of Medical Science, 5th kilometer of Fahraj-Khavidak
road, Yazd

City

Yazd

Postal code**Approval date**

2013-06-10, 1392/03/20

Ethics committee reference number

48450

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

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

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

Weight

Timepoint

Before intervention and once a month after

Method of measurement

Scale with accuracy 100 gr

2**Description**

Body Mass Index (BMI)

Timepoint

Before intervention and then once a month after

Method of measurement

Calculation: Weight (kg) / squared height (m)

3**Description**

Waist

Timepoint

Before intervention and then once a month after

Method of measurement

Tape meter

4**Description**

Body Fat Mass

Timepoint

Before intervention and once a month after

Method of measurement

Body Composition Instrument

5**Description**

Serum leptin levels

Timepoint

Before and after intervention

Method of measurement

ELISA kit

Secondary outcomes**1****Description**

Height

Timepoint

Before intervention and then once a month after

Method of measurement

Tape meter installed on the wall

2**Description**

Total energy intake

Timepoint

Before and after intervention

Method of measurement

24 hour recall

3

Description

Total carbohydrate intake

Timepoint

Before and after intervention

Method of measurement

24 hour recall

4

Description

Total fat intake

Timepoint

Before and after intervention

Method of measurement

24 hour recall

5

Description

Total protein intake

Timepoint

Before and after intervention

Method of measurement

24 hour recall

6

Description

Total Chromium intake

Timepoint

Before and after intervention

Method of measurement

24 hour recall

Intervention groups

1

Description

In intervention group, obese or overweight individuals, aged 20 to 50, will receive a daily 200 mcg Chromium Picolinate and do 30 minutes exercise. The subjects are told not to change diet and life style.

Category

Treatment - Drugs

2

Description

In control group, obese and overweight individuals, aged 20-50 years, will receive no intervention. The subjects are told not to change diet and life style.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi University of Medical Science

Full name of responsible person

Dr. Azade Najarzadeh

Street address

Health School, Daneshjoo Blvd, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Sadoughi University of Medical Science, International branch

Full name of responsible person

Dr. Mohammad Hasan Sheikhha

Street address

International campus of Shahid Sadoughi University of Medical Science, 5th kilometer of Fahraj-Khavidak road, Yazd

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Sadoughi University of Medical Science, International branch

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Sadoughi University of Medical Science

Full name of responsible person

Dr. Hasan Mozaffari Khosravi

Position

PhD of Nutrition, professor

Other areas of specialty/work**Street address**

Health School, Daneshjoo Blvd, Yazd

City
Yazd
Postal code
89156-887
Phone
+98 35 1624 5900
Fax
+98 35 1623 8555
Email
mozaffari.kh@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Sadoughi University of Medical Science-
Intrnational branc
Full name of responsible person
Peyvand Robati
Position
Msc student of health science in nutrition
Other areas of specialty/work
Street address
International campus of Shahid Sadoughi University

of Medical Science, 5th kilometer of Fahraj-Khavidak
road, Yazd
City
Yazd
Postal code
Phone
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty