

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### Effects of Chromium Picolinate on Glycemic Index, Lipid Profile ,Gene Expression of Inflammatory Biomarkers and DNA damage in Metabolic Syndrome Patients

#### Protocol summary

##### Study aim

Determining the effect of trivalent chromium picolinate supplementation on glycemic indexes , lipid profiles, gene expression of some inflammatory mediators and DNA damage in metabolic syndrome patients

##### Design

Randomized controlled clinical trial with two arm parallel group, patients(n=48) will be randomly divided into equal two groups of intervention or placebo using computer software Random-Number Generator

##### Settings and conduct

Sisakht City Adult Cohort Study. Anthropometric and biochemical indicators will be measured before and after 12 weeks of intervention. The patients themselves, the principal investigator, the laboratory technician and statistical analyzer will not be aware of the grouping of participants and only a trusted health expert will be aware. The tablets received by the two groups will be the same in terms of packaging, smell, color and appearance.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having the metabolic syndrome

Exclusion criteria: - take any multivitamins or dietary supplements or medications, Pregnancy and lactation, uncontrolled blood pressure, uncontrolled blood sugar, heart arrhythmias and chronic obstructive pulmonary disease, stroke or any other disease that requires medical treatment

##### Intervention groups

Intervention in the first group: 400µg of trivalent chromium picolinate tablets (21 st CENTURY, US company) Intervention in the first group: matched placebo tablets chromium picolinate

##### Main outcome variables

Glycemic index, Lipid Profile ,Gene Expression of Inflammatory Biomarkers and DNA damage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200919048757N1**

Registration date: **2020-10-18, 1399/07/27**

Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

##### Registration date

2020-10-18, 1399/07/27

##### Registrant information

##### Name

Behrooz Ebrahimzadehkoor

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3334 6078

##### Email address

ebrahimzadeh1358@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-10, 1399/08/20

##### Expected recruitment end date

2021-01-29, 1399/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effects of Chromium Picolinate on Glycemic Index, Lipid Profile, Gene Expression of Inflammatory Biomarkers and DNA damage in Metabolic Syndrome Patients

**Public title**

effects of chromium picolinate in metabolic syndrome

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Metabolic syndrome characterized by "at least three of the five conditions: - waist circumference  $\geq 94$  cm - systolic blood pressure and diastolic greater than or equal to 130 and 85 mm Hg respectively or blood pressure lowering medication use - Fasting Blood Sugar  $\geq 100$  mg / dl or hypoglycemic drugs use - Blood triglycerides  $\geq 150$  mg / dl or lipid-lowering drugs use - HDL  $< 50$  mg/dl in women and less than 40 mg/ dl in Men"

**Exclusion criteria:**

take any multivitamins or dietary supplements or medications Pregnancy or lactation uncontrolled hypertension or hyperglycemia chronic obstructive pulmonary disease heart arrhythmias stroke any other disease that requires medical treatment

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the first stage, from registered information of people in the Sisakht city Adult Cohort Center, all eligible persons will be listed and numbered. Then, 48 patients will be randomly selected using Random Numbers Generator software. In the next step, based on above mentioned software as a random sequencing tool, patients will be divided into two intervention groups A (intervention) and B (placebo).

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Patients participating in the study, laboratory technician, statistical analyst and researcher will not be aware from patient grouping until the end of the study and only a trusted health expert who has no involvement in the process of study will be informed. The tablets received by both groups will be the same in terms of color, smell and appearance. The label of the boxes containing the

tablets will be removed and only will be marked with a special code.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

institutional research ethics committee of school of public health-Shahid Sadooghi university of medicine

**Street address**

N.887, Shohadaye Gomonam Blvd, Alem Sq. Pardis olompezeski- school of public health

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Approval date**

2020-09-09, 1399/06/19

**Ethics committee reference number**

IR.SSU.SPH.REC.1399.141

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

metabolic syndrome

**ICD-10 code**

E88.81

**ICD-10 code description**

Metabolic syndrome

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

Glycemic Index (Fasting Blood Sugar, Glycosylated Hemoglobin)

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

enzymatic colorimetric method

**2****Description**

Lipid Profile (TG, TC, LDL, HDL)

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

enzymatic colorimetric method

**3****Description**

DNA damage(hydroxy-deoxyguanosine)

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

Enzyme Linked Immunosorbent Assay (ELISA)

**4****Description**

Interleukin-1

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

Enzyme Linked Immunosorbent Assay (ELISA)

**5****Description**

Interleukin-6

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

Enzyme Linked Immunosorbent Assay (ELISA)

**6****Description**

Tumor Necrosing Factor- $\alpha$

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

Enzyme Linked Immunosorbent Assay (ELISA)

**7****Description**

Gene Expression of Inflammatory Biomarkers (Tumor Necrosing Factor- $\alpha$ )

**Timepoint**

Beginning of the study and at the end of the study (end of the fourth month)

**Method of measurement**

reverse transcription polymerase chain (RT-PCR)

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

weight

**Timepoint**

The beginning of the study and the end of the fourth month

**Method of measurement**

standard scale

**2****Description**

waist circumference

**Timepoint**

The beginning of the study and the end of the fourth month

**Method of measurement**

non-stretching tape

**3****Description**

blood pressure

**Timepoint**

The beginning of the study and the end of the fourth month

**Method of measurement**

Blood pressure monitor

**Intervention groups****1****Description**

Intervention group:daily intake of 400 $\mu$ g of trivalent chromium picolinate tablets (21 st CENTURY, US company) for 12 weeks

**Category**

Prevention

**2****Description**

Control group: daily intake of matched placebo tablet made by Barij Essential Oil Company for 12 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sisakht City Adults Health Prospective Cohort Study Center , University of Medical Sciences-

**Full name of responsible person**

Behrooz Ebrahimzadehkoor

**Street address**

Shahid Motahari Blvd, Jihad Keshavaezi Sq.

**City**

Yasouj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6078

**Email**

ebrahimzadeh1358@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Hasan MozaffariKhosravi

**Street address**

N.887, Shohadaye Gomnam Blvd,Alam Sq.  
Daneshgah Blvd.Public Health School

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Phone**

+98 35 3149 2137

**Email**

mozaffari.kh@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Behrooz Ebrahimzadehkoor

**Position**

Candidate for PhD- Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Shahid Motahhari Blvd,Jehad Keshavarzi Sq, Yasouj

University of medical sciences

**City**

Yasouj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

009833346074

**Email**

ebrahimzadeh1358@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Behrooz Ebrahimzadeh koor

**Position**

Candidate of PhD- Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Shohadaye Gomnam Blvd, Jihad Keshavarzi Sq, Yasouj  
University of Medical Sciences

**City**

Yasouj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6074

**Email**

ebrahimzadeh1358@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Behrooz Ebrahimzadehkoor

**Position**

Candidate of PhD- Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Shohadaye Gomnam Blvd,JJehad Keshavarzi Sq, Yasouj  
University of medical sciences

**City**

Yasouj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6074

**Email**

ebrahimzadeh1358@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to

make this available

**Title and more details about the data/document**

data related to anthropometric and biochemical data and the extent of their changes

**When the data will become available and for how long**

6 months after the publication of the main article

**To whom data/document is available**

Researchers working in academic and scientific institutions and working in industry

**Under which criteria data/document could be used**

Statistical analysis is allowed provided the source of the data is mentioned and with the permission of the authors of the article

**From where data/document is obtainable**

behrooz ebrahimzadeh koor (Yasuj University of medical sciences) hasan mozaafari (Yazd University of medical sciences)

**What processes are involved for a request to access data/document**

email and postal letter

**Comments**