Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥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≥ 100 mg / dl or hypoglycemic drugs use - Blood triglycerides ≥150 mg / dl or lipid-lowering drugs use - HDL<50mg/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 cityAdult 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 committe of school of public health-Shahid sdoughi university of medic
Street address
N.887, Shohadaye Gomnam Blvd, Alem Sq. Pardis oloompezeshki- school of public health
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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-α
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-α)
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 400µg 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
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Sponsors / Funding sources

1

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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
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
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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 andworking 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 mozaffari (Yazd University of medical sciences)
What processes are involved for a request to access data/document
email and postal letter
Comments