Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

The effect of oral Chromium picolinate supplementation on Liver Function, Oxidative Indicators, Leptin, Resisten, lipid profile, Blood Glucose Control Indicators, serum levels of Fetuin A and inflammatory factors in Non-Alcoholic Fatty Liver

Protocol summary

Study aim

Determine the effect of oral Chromium picolinate supplementation on Liver Function, Oxidative Indicators, Leptin, Resisten, lipid profile, Blood Glucose Control Indicators, serum levels of Fetuin A and inflammatory factors in Non-Alcoholic Fatty Liver (NAFLD)

Design

In this study, the target population will be people with NAFLD who were diagnosed and introduced by a gastroenterologist and ultrasound specialists and entered the study according to the criteria for entering the study and after obtaining written consent, randomly divided into two control and intervention groups.

Settings and conduct

This double-blind study is conducted at the Faculty of Nutrition Sciences of Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients with NAFLD and lack of non-compliance characteristics

Intervention groups

Group intervention group receiving chromium picolinate and control group of starch corn.

Main outcome variables

Body mass index (BMI); age; duration of disease; history of drug use; diet; psychological stress; physical activity; Total cholesterol (TC); Triglyceride (TG); low density lipoprotein (LDL); High density lipoprotein (HDL); Plasma Atherosclerosis; Haemoglobin A1c (HbA1c) ; Insulin serum concentration; Fasting blood glucose; Insulin resistance index; Fetuin A; Tumour necrosis factor-α (TNF-α); High-sensitivity C-reactive protein (Hs-CRP); Interleukin 17 (IL-17); Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Alkaline Phosphatase (ALP) ; Superoxide Dismutase (SOD); Malondialdehyde (MDA); Glutathione Peroxidase (GPX); leptin; Resistin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100123003140N15**
Registration date: **2018-01-14, 1396/10/24**
Registration timing: **prospective**

Last update: **2018-01-14, 1396/10/24**
Update count: **0**

Registration date

2018-01-14, 1396/10/24

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1435 7580

Email address

pourghassemb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-07-13, 1397/04/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral Chromium picolinate supplementation on Liver Function, Oxidative Indicators, Leptin, Resisten, lipid profile, Blood Glucose Control Indicators, serum levels of Fetuin A and inflammatory factors in Non-Alcoholic Fatty Liver

Public title

The effect of Chromium picolinate in Non-Alcoholic Fatty Liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who agree to participate in the study Men and women aged 20 to 50 years BMI ranges from 25 to 40 kg / m 2 Increased levels of ALT and AST are higher than normal levels Grade 2, 3, and 4 diseases

Exclusion criteria:

kidney disease Thyroid gland problems Uncontrolled blood pressure Taking statin Hepatitis C and B Cytomegalovirus Pregnancy alcohol consumption Wilson Hocromatosis Deficiency of alpha-1 antitrypsin

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were randomly assigned to either one of the two groups of chromium picolinate or placebo using RAS software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are assigned codes and randomly divided into placebo and intervention groups. Both patients and us will not be aware of which patients will take placebo or supplement

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

No 2 Central Building, Tabriz University of Medical Science, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-01-01, 1396/10/11

Ethics committee reference number

IR.TBZMED.REC.1396.924

2

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-01-01, 1396/10/11

Ethics committee reference number

IR.TBZMED.REC.1396.925

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

LDL

Timepoint

First and three months after the start of the study

Method of measurement

Enzyme colorimetry

2

Description
HDL
Timepoint
First and three months after the start of the study
Method of measurement
Enzyme colorimetry

3

Description
TNF-α
Timepoint
First and three months after the start of the study
Method of measurement
ELISA Kit

Secondary outcomes

1

Description
Plasma Atherogen Index
Timepoint
Study beginning and 90 days after the start
Method of measurement
Triglyceride logarithmic formulation divided by high density lipoprotein

2

Description
BMI
Timepoint
First and six weeks after study
Method of measurement
Weight divided by second power of height

3

Description
Dietary intakes
Timepoint
First and 6 weeks after the start
Method of measurement
24-hour dietary recall inventory questionnaire

4

Description
Psychological stress
Timepoint
First and six weeks after the start of the study
Method of measurement
Holmes-and rahe scales questionnaire

5

Description
Insulin resistance index
Timepoint
First and three months after the studyفر
Method of measurement
Calculate Homeostatic model assessment

6

Description
The amount of physical activity
Timepoint
First and 6 weeks after study
Method of measurement
The International Physical Activity Questionnaire

7

Description
Waist circumference
Timepoint
First and Sixth Week
Method of measurement
measurement

8

Description
Boddy fat mass
Timepoint
First and Sixth Week
Method of measurement
Bioelectrical impedance analysis

9

Description
blood pressure
Timepoint
Frist and sixth week
Method of measurement
Digital monometer

10

Description
Chromium levels of blood
Timepoint
First and 3 months later study
Method of measurement
Spectrophotometry

11

Description
SOD
Timepoint
First and three months after the start of the study
Method of measurement
Biochemical kit

12

Description
ALP
Timepoint

First and three months after the start of the study

Method of measurement

Biochemical kit

13

Description

AST

Timepoint

First and three months after the start of the study

Method of measurement

Biochemical kit

14

Description

resistin

Timepoint

First and three months after the start of the study

Method of measurement

ELISA Kit

15

Description

Leptin

Timepoint

First and three months after the start of the study

Method of measurement

ELISA Kit

16

Description

MAD

Timepoint

First and three months after the start of the study

Method of measurement

Biochemical kit

17

Description

GPX

Timepoint

First and three months after the start of the study

Method of measurement

Biochemical kit

18

Description

ALT

Timepoint

First and three months after the start of the study

Method of measurement

Biochemical kit

19

Description

IL-17

Timepoint

First and three months after the start of the study

Method of measurement

ELISA kit

20

Description

Hs-CRP

Timepoint

First and three months after the start of the study

Method of measurement

ELISA Kit

21

Description

Concentration of Fetuin A

Timepoint

First and three months after the start of the study

Method of measurement

ELISA Kit

22

Description

Serum insulin concentration

Timepoint

First and three months after the start of the study

Method of measurement

ELISA Kit

23

Description

HbA1c

Timepoint

First and three months after the start of the study

Method of measurement

ELISA Kit

24

Description

TG

Timepoint

First and three months after the start of the study

Method of measurement

Enzyme colorimetry

25

Description

TC

Timepoint

First and three months after the start of the study

Method of measurement

Enzyme colorimetry

26

Description

Fasting blood sugar

Timepoint

First and three months after the start of the study

Method of measurement

Enzyme colorimetry

Intervention groups

1

Description
patients with NAFLD receiving 2 tablets of 200 microgram of chromium picolinate per day for 3 months. Delivery of medication to patients will be done every two weeks and it will be monitored during use by the phone for possible complications and continued use.
Category
Treatment - Other

2

Description
Control group:Patients with NAFLD who receive a placebo of corn starch tablets for two days each day for 3 months. Placebo will be delivered to patients every two weeks and will be monitored by the phone for potential side effects and continued use during use.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz International Hospital
Full name of responsible person
Manouchehr khoshbaten
Street address
Tabriz International Hospital, First Zaferanieh, Aflakat Square
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3332 8832
Email
mkhoshbaten@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
Faculty of Nutrition and food science, Tabriz University of Medical Sciences, Golgasht st, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 7581
Email
ostadrahimi@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Bahram Pourghasem Gargari
Position
Faculty Member and Professor of Nutrition Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Faculty of Nutrition and food science, Tabriz University of Medical Sciences, Golgasht st, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3336 2117
Email
pourghassemb@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person

Bahram Pourghasem Gargari

Position
Faculty Member and Professor of Nutrition Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Faculty of Nutrition and food science, Tabriz University of Medical Sciences, Golgasht st, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Phone
+98 41 3335 7581

Email
pourghassemb@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Bahram Pourghasem Gargari

Position
Faculty Member and Professor of Nutrition Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Faculty of Nutrition and food science, Tabriz University of Medical Sciences, Golgasht st, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Phone
+98 41 3335 7581

Email
pourghassemb@tbzmed.ac.ir

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
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

Title and more details about the data/document
Publish primary and raw results of samples

When the data will become available and for how long
Then finish and publish the draft articles

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
With the permission of the researcher of the project and the sponsor of the project, the Nutrition Research Center and the Research Assistant of the University

From where data/document is obtainable
To the Nutrition Research Center - Scheme researchers

What processes are involved for a request to access data/document
In-person attendance and relevant permissions - phone call

Comments