Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of chromium picolinate supplementation on insulin resistance, liver enzymes, steatosis and fibrosis in individuals with normal weight and metabolic dysfunction-associated steatotic liver disease: A parallel double-blind randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of chromium picolinate supplementation on insulin resistance, liver enzymes, steatosis and fibrosis in individuals with normal weight and metabolic dysfunction–associated steatotic liver disease

Design

A parallel randomized, double-blinded, controlled trial on 80 MASLD patients (40 in each group). Stratified block-randomization based on BMI is used.

Settings and conduct

This study will be conducted on 80 MASLD patients referred to gastroenterology clinic in Tehran, Iran. Patients will be randomly divided into 2 equal groups and will receive chromium picolinate and placebo for 12 weeks. To blind all researchers and participants, supplement and placebo are similar in appearance and color and a third person outside the study knows their content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 y adults of both genders; BMI of 18.5 to 25; diagnosis to have MASLD based on fibroscan by a gastroenterologist. Exclusion criteria: alcohol consumption; pregnant/lactating females; having other liver diseases (hepatitis B and C), biliary diseases, autoimmune diseases, cancer, kidney diseases, thyroid diseases, and diabetes; use blood sugar-lowering drugs and insulin; use of medications that affect liver fat, corticosteroids, antibiotics, hepatotoxic medications, and levothyroxine; weight loss in the last 3 months; withdrawal to continue the study; weight loss more than 10% during the study; pregnancy during the study; any severe gastrointestinal complications related to the intervention.

Intervention groups

Two groups (n=40 in each): intervention group (1 tablet containing 500 mcg chromium picolinate per day) and placebo group (1 tablet per day of corn starch).

Main outcome variables

Primary outcome: changes in liver steatosis; Secondary outcome: FBS, serum insulin, HOMA-IR, QUICKI, ALT, AST, GGT, fibrosis, weight, waist circumference, adverse events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250222064808N1**
Registration date: **2025-04-13, 1404/01/24**
Registration timing: **prospective**

Last update: **2025-04-13, 1404/01/24**
Update count: **0**

Registration date

2025-04-13, 1404/01/24

Registrant information

Name

Keyhan Lotfi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01
Expected recruitment end date
2026-06-22, 1405/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of chromium picolinate supplementation on insulin resistance, liver enzymes, steatosis and fibrosis in individuals with normal weight and metabolic dysfunction-associated steatotic liver disease: A parallel double-blind randomized controlled clinical trial

Public title
Chromium picolinate in metabolic dysfunction-associated steatotic liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults (male and female) in the age range of 18-65 years Have a body mass index of 18.5 to 25 Diagnosis of MASLD based on fibroscan by a gastroenterologist and in the range (7.3-17.6 kPa for fibrosis and greater than 238 dB/m for steatosis)
Exclusion criteria:
Alcohol consumption Pregnant or lactating females Having other liver diseases (including hepatitis B and C), biliary diseases, autoimmune diseases, cancer, kidney diseases, thyroid diseases, and diabetes Use of blood sugar-lowering drugs and insulin Use of medications that affect liver fat, corticosteroids, antibiotics, hepatotoxic medications, and levothyroxine Weight loss in the last 3 months Withdrawal from study follow-up Weight loss more than 10% during the study Pregnancy during study The occurrence of any severe gastrointestinal complications related to the intervention (headache, diarrhea, vomiting, abdominal pain)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
At the beginning of the study and before the intervention, random assignment of individuals to intervention groups will be done using the Stratified Block Randomization method. First, individuals will be grouped based on BMI (18.5 to 20.5, 20.5 to 22.5, and 22.5 to 25), and in each of these blocks, individuals who are matched in terms of BMI will be placed. Then, in each block, individuals will be randomly divided into two supplement and placebo groups. Randomization will be done using the Random Allocation Software (RAS). In this method, each group will be assigned one of the letters A and B, and randomization will be done in blocks of 4. Within each stratum, individuals will be randomly placed in one of the two study groups in a 1:1 ratio.
Blinding (investigator's opinion)
Double blinded
Blinding description
The present study will be conducted in a double-blind manner, meaning that the participants, the principal investigator, and the evaluators will not identify individuals receiving the chromium picolinate supplement or the placebo. The appearance, color, taste, and odor of the chromium supplement and the placebo will be similar. As a result, the study participants will not know which supplement/placebo they were taking. Also, the supplements/placebos will be coded, and a person outside the study will know the codes and the type of supplement/placebo. The evaluators will deliver the supplements/placebos to the participants based on the code labeled on them and will not know the content of each supplement.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee of school of medicine-Tehran University of Medical Sciences
Street address
Keshavarz Blvd
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Tehran
Postal code
1416643931
Approval date
2025-02-26, 1403/12/08
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.627

Health conditions studied

1

Description of health condition studied
Metabolic dysfunction–associated steatotic liver disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Changes in liver steatosis
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Fibroscan

Secondary outcomes

1

Description
Liver fibrosis
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Fibroscan

2

Description
Fasting blood sugar
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Glucose oxidase

3

Description
Serum insulin
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Elisa kit

4

Description
HOMA-IR
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Formula: HOMA-IR = (fasting insulin (µU/L) × fasting glucose (mmol/L))/22.5

5

Description
QUICKI
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Formula: QUICKI= 1 / (log (fasting insulin µU/mL) + log (fasting glucose mg/dL))

6

Description
Alanine transaminase (ALT)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Colorimetric determination

7

Description
Aspartate transaminase (AST)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Colorimetric determination

8

Description
Gamma-glutamyl transferase (GGT)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Colorimetric determination

9

Description
Weight
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement

Digital scale

10

Description
Waist circumference
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Measurement tape

11

Description
Adverse events
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after 12 weeks of intervention)
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Patients in this group will receive chromium picolinate tablets including 500 mcg chromium once a day for 12 weeks. Tablets are made in Iran.
Category
Treatment - Other

2

Description
Control group: Patients in this group will receive placebo for 12 weeks. The placebo is corn starch and will be consumed once a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masoud Gastroenterology and Liver Clinic
Full name of responsible person
Keyhan Lotfi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd.
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Web page address
https://snsd.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
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Ahmad Esmaillzadeh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The study protocol will be written and published in the form of an article. The clinical report of the study will be published in the form of an article.

When the data will become available and for how long
8 months after the end of the study

To whom data/document is available
The data will only be available for people working in academic institutions.

Under which criteria data/document could be used
To use the findings in the clinic or to write other articles, including review articles. In the case of original articles, researchers will be allowed to do so.

From where data/document is obtainable
Data and documents related to the present study will be available via email from the study researchers, Dr. Ahmad Esmaillzadeh (a.esmaillzadeh@gmail.com) and Keyhan Lotfi (keyhanlotfi75@gmail.com).

What processes are involved for a request to access data/document
After receiving the request from the person in charge of updating, the study will be provided to the researcher in consultation with the scientific officer.

Comments