

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

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

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Keshavarz Blvd

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Province

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: $\text{HOMA-IR} = (\text{fasting insulin } (\mu\text{U/L}) \times \text{fasting glucose } (\text{mmol/L})) / 22.5$

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: $\text{QUICKI} = 1 / (\log (\text{fasting insulin } \mu\text{U/mL}) + \log (\text{fasting glucose mg/dL}))$

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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Web page address

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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

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

Full name of responsible person

Ahmad Esmailzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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 Esmailzadeh (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