

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of chromium administration on mean serum levels of HbA1C, FBS and 2hpp in diabetic patients: A double-blind randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of chromium drug administration on the mean serum levels of HbA1C, FBS and 2hpp in diabetic patients

Design

Clinical trial with an intervention group, with a parallel group; One side blind, random

Settings and conduct

This study is conducted in Waliassr Hospital, Birjand, South Khorasan Province. 50 patients are randomly divided into two intervention groups, one or two (A-B). Questions related to the effectiveness of the intervention before and 3 months after the treatment will be collected and evaluated by the blood sample operator.

Participants/Inclusion and exclusion criteria

Our study population will be diabetic patients living in the city of Birjand referring to the diabetes clinic and the specialized clinic of Valiasr Hospital in Birjand in 2023. Inclusion criteria 1. Age over 40 years 2. Patients with type 2 diabetes 3. Having diabetes for at least 6 months 4. Patients treated with oral medicine 5. Glycosylated hemoglobin below 9 Exclusion criteria 1. Patients consuming minerals, vitamins or antioxidants or medicinal plants 2. Pregnant or lactating women 3. Disease with heart failure 4. Having another chronic disease 5. Thyroid problems, either hypo or hyperthyroid 6. Treatment of hyperlipidemia 7. Having complications of diabetes including retinopathy, neuropathy and nephropathy 8. Receiving insulin 9. Patients with kidney and liver failure 10. Patients undergoing treatment for gastrointestinal diseases

Intervention groups

The intervention groups are as follows: intervention group A received chromium picolinate tablets 200 mg twice a day (after meals and on a full stomach) for 3 months, and in control group B, patients took their routine diabetes medications. And 3 months later they

refer for evaluation.

Main outcome variables

Fasting blood sugar (FBS): Glycosylated hemoglobin (HbA1C): Blood sugar 2 hours after eating (2hpp)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N19**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-22, 1402/04/31

Expected recruitment end date

2023-12-20, 1402/09/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of chromium administration on mean serum levels of HbA1C, FBS and 2hpp in diabetic patients: A double-blind randomized controlled clinical trial

Public title
The effect of chromium administration on the mean serum levels of HbA1C, FBS and 2hpp in diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 40 years Patients with type 2 diabetes Having diabetes for at least 6 months Patients treated with oral medication Glycosylated hemoglobin below 9
Exclusion criteria:
 Patients consuming minerals, vitamins or antioxidants or medicinal plants Pregnant or lactating women Heart failure disease Having another chronic disease Treatment of hyperlipidemia Having complications of diabetes including retinopathy, neuropathy and nephropathy Receive insulin Patients with kidney and liver failure Patients undergoing treatment for gastrointestinal diseases Thyroid problems, either hypo or hyperthyroid

Age
From **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
The placement of people in each group will be simple random and in a block method, in one of the two groups A (chromium picolinate tablets 200 mg twice a day after meals and with a full stomach for 3 months), the intervention B (take their routine diabetes medications and will be placed for 3 months). In this way, first, various blocks of four (AABB, BBAA, ABAB, BABA, ABBA and BABA) are created on different cards. One of these blocks will be randomly selected using the lottery method and the patients will be divided into one of two groups A or B. Then randomization is done for other patients as well. This will be done by the secretary.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome evaluator: The study leader (3rd year internal medicine assistant) and the laboratory expert, without

knowing the type of drug received by the patients, takes the necessary samples and sends them to the laboratory for examination.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Birjand University of Medical Sciences
Street address
 Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.
City
 Birjand
Province
 South Khorasan
Postal code
 9717811674

Approval date
2022-09-05, 1401/06/14

Ethics committee reference number
IR.BUMS.REC.1401.226

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Fasting Blood Sugar

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
in serum samples of patients using the Bionic company kit

2

Description

Glycosylated hemoglobin

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

in serum samples of patients using the Bionic company kit

3

Description

Fasting blood sugar 2 hours after eating

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

in serum samples of patients using the Bionic company kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group: Group A receiving chromium picolinate tablets 200 mg twice a day (after meals and on a full stomach) for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group: Group B receiving routine diabetes medications for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Birjand Hospital

Full name of responsible person

Dr.Erfan Zeratkar

Street address

Valiasr Hospital Diabetes Clinic. Ghafari Blvd, Birjand, South Khorasan, Iran.

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Phone

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Email

Valiasrhospital@bums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Miri

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr. Erfan Zeratkar

Position

Internal resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

School of Medicine, Birjand University of medical sciences, Ghahhari Blvd, Birjand, South Khorasan, Iran.

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Anahita Aryan

Position

Member of the Faculty

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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