

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of chromium on the metabolic index in patients with diabetes mellitus type2

Protocol summary

Summary

The point of this plan is finding out chromium effect on diabetes based on metabolic indices such as BS, TG, Cholesterol, LDL, HDL, HbA1c, weight and BMI. Design: Randomized, double blind, placebo controlled, one central. Inclusion criteria: $7\% \leq \text{HbA1c} \leq 10$, $25 \leq \text{BMI} \leq 35$, DM2, having stability of anti diabetic treatment during 3 month, having 30 to 65 years old. They will be excluded from the study in the case of having $\text{Cr} > 1.5$ for male and $\text{Cr} > 1.4$ for female, liver enzymes (Alt, Ast) more than two upper limit normal, pregnancy, heart failure, chronic liver disease, uncontrolled hypertension, immunosuppressive disease or immunosuppressive treatment, alcohol use and other drug abuse, psychological unhealthy, confined to bed during recent 1 years. In this research 60 type2 diabetic patients will be chosen for administration of 200 micro grams chromium picolinate tablet (intervention group) or placebo (control group) during 3 months then we will measure index of HbA1c, LDL, HDL, TG, Cr, FBS, Bs2hpp, Uric acid, Alt, Ast, BMI before and 3 month after intervention and the results will be compared for this two groups based on response the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012812311N1**

Registration date: **2013-03-07, 1391/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-07, 1391/12/17

Registrant information

Name

Azam Erfanifar

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4484 7836

Email address

erfanifarazam@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigators

Expected recruitment start date

2012-05-14, 1391/02/25

Expected recruitment end date

2012-09-08, 1391/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of chromium on the metabolic index in patients with diabetes mellitus type2

Public title

Effect of chromium on diabetes mellitus type2 treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. $\text{HbA1c} \leq 10\%$, $\text{HbA1c} \geq 7\%$; 2. DM2; 3. $\text{BMI} \leq 35$, $\text{BMI} \geq 25$; 4. Stability of antidiabetic treatment during recent 3 months; 5. Age 30-65 years. Exclusion criteria: 1. $\text{Cr} > 1.5$ (men), $\text{Cr} > 1.4$ (female); 2. Liver function test (ALT, AST) > 2 fold of upper limit normal; 3. Pregnancy; 4. Heart Failure; 5. Chronic Liver disease; 6.

Uncontrolled hypertension; 7. Immunosuppression disease and immunosuppressive therapy; 8. Alcohol use and other drug abuse; 9. Psychological unhealthy; 10. Confined to bed during recent 1 years.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak-evin

City

Tehran

Postal code

Approval date

2012-05-13, 1391/02/24

Ethics committee reference number

117

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Uric acid

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

2

Description

HbA1c

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

3

Description

HDL- C

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

4

Description

LDL- C

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

5

Description

TG

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

6

Description

FPG

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

7

Description

BS 2hpp

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

8

Description

BMI

Timepoint

Before intervention & 3 months later

Method of measurement

kg/m2

9

Description

Creatinine

Timepoint

Before intervention & 3 months later

Method of measurement

mg/dl- laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: chromium picolinate 200 microgram tablet, once daily during 3 months.

Category

Treatment - Drugs

2

Description

control group: placebo, once daily during 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hospital

Full name of responsible person

Dr. Saeid Kalbasi

Street address

Makhsous Ave, Lashkar Croosroads, South Kargar Ave.

City

Tehran

2

Recruitment center

Name of recruitment center

Taban Clinck of Diabetic disease Control

Full name of responsible person

Dr. Saeid Kalbasi

Street address

No 100, north Derakhti Blvd, shahid Dadman Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

Doctor Azam Erfanifar

Street address

Tehran-Punak

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Private

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Doctor Hosein Gudarzi

Street address

Velenjak- Evin

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Doctor Azam Arfanifar

Position

Internal Medicine resident

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Web page address**Email**

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty