Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Simultaneous use of chromium picolinate and vitamin D reconstruction or prevention of endothelial dysfunction in patients with type 2 diabetes by examining the pattern of changes in metabolic markers of oxidative stress, inflammation and endothelial dysfunction

Protocol summary

Summary

The aim of the study was to investigate the effects of simultaneous use of vitamin D and chromium picolinate on the markers of oxidative stress, inflammation, glucose, lipids and endothelial dysfunction in patients with type2. Inclusion criteria included patients with type 2 diabetes for up to 5 years with metformin as medicine and with age ranging from 25 to 65. Exclusion criteria included patients with insulin injections, inflammatory diseases, kidney disease, liver diseases, parathyroid disease, pregnancy and lactation, anticonvulsant and steroid use, history of smoking, use of supplements and minerals, hyper and hypothyroidism. The total sample size was 96 patients were divided in 4 groups of 24 people. The first group received placebo, the second group received chromium picolinate, the third group received vitamin and fourth group received chromium picolinate and vitamin D simultaneously for 6 months. It is expected that consumption of these supplements improves lipid, oxidative stress and inflammation patterns and endothelial dysfunction in these patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052034038N1**
Registration date: **2017-06-14, 1396/03/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-14, 1396/03/24

Registrant information

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Name of organization / entity
Khomein University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Khomein University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Simultaneous use of chromium picolinate and vitamin D reconstruction or prevention of endothelial dysfunction in patients with type 2 diabetes by examining the pattern of changes in metabolic markers of oxidative stress, inflammation and endothelial dysfunction

Public title

Prevention of endothelial dysfunction in patients with type 2 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

(Inclusion criteria: patients with type 2 diabetes for a maximum of 5 years; 25 to 60 years ages; with metformin as a hypoglycemic medication) (Exclusion criteria: patients with Insulin injection; inflammatory diseases; kidney disease; liver disease; parathyroid disease; pregnancy and lactation; taking anticonvulsants and steroids; history of tobacco; the use of supplements and minerals ; patients with hypertension and hypothyroidism)

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Markazi Province university of Medical Sciences and Health Services,

Street address

Assistance Education and Research, On the campus of University of Medical Sciences, Basij square, Arak

City

Arak

Postal code

Approval date

2017-03-08, 1395/12/18

Ethics committee reference number

IR.ARAKMU.REC.1395.466

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Before and after the intervention.

Method of measurement

KIT

2

Description

Oral glucose tolerance test

Timepoint

Before and after the intervention.

Method of measurement

KIT

3

Description

glycated haemoglobin (HbA1C)

Timepoint

Before and after the intervention.

Method of measurement

KIT

4

Description

Cholesterol of LDL

Timepoint

Before and after the intervention.

Method of measurement

KIT

5

Description

HDL-C

Timepoint

Before and after the intervention.

Method of measurement

KIT

6

Description

TRIGLYCERIDE

Timepoint

Before and after the intervention.

Method of measurement

KIT

7

Description
TOTAL CHOLESTROL
Timepoint
Before and after the intervention.
Method of measurement
KIT

8

Description
Tumor necrosis factor alpha (TNF-α)
Timepoint
Before and after the intervention.
Method of measurement
KIT

9

Description
Malondialdehyde (MDA)
Timepoint
Before and after the intervention.
Method of measurement
KIT

10

Description
Total thiols OF PROTIENS
Timepoint
Before and after the intervention.
Method of measurement
KIT

11

Description
the total antioxidant capacity
Timepoint
Before and after the intervention.
Method of measurement
KIT

12

Description
Soluble Vascular Cell Adhesion Molecule-1 (sVCAM-1)
Timepoint
Before and after the intervention.
Method of measurement
KIT

13

Description
Plasminogen activator inhibitor type 1 (PAI-1)
Timepoint
Before and after the intervention.
Method of measurement
KIT

14

Description
INSULIN
Timepoint
Before and after the intervention.
Method of measurement
KIT

15

Description
CHROMIUM
Timepoint
Before and after the intervention.
Method of measurement
KIT

16

Description
25(OH) D3
Timepoint
Before and after the intervention.
Method of measurement
KIT

17

Description
CALCIUM
Timepoint
Before and after the intervention.
Method of measurement
KIT

18

Description
PHOSPHOR
Timepoint
Before and after the intervention.
Method of measurement
KIT

19

Description
parathyroid hormone test
Timepoint
Before and after the intervention.
Method of measurement
KIT

Secondary outcomes

empty

Intervention groups

1

Description
The second group: receiving 400 microgram of chromium

picolinate daily for 6 months

Category

Treatment - Drugs

2

Description

The third group: receiving vitamin D for 6 months, per week 50,000 IU

Category

Treatment - Drugs

3

Description

the first group: the control group received a placebo for 6 months.

Category

Treatment - Drugs

4

Description

fourth Group : receiving Vitamin D and chromium picolinate for six months, 50,000 units per week and 400 micrograms for per day, respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Javad javaheri

Street address

City

Khomein

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khomein University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Imanparast

Street address

Khomein University of Medical Sciences, Quds Boulevard, Khomein

City

Khomein

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khomein University of Medical Sciences

Proportion provided by this source

100

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

Khomein University of Medical Sciences

Full name of responsible person

dr.Fatemeh Imanparast

Position

Science Committee

Other areas of specialty/work

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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