# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effects of the simultaneous use of chromium and vitamin D supplements on hemosysteien in type 2 diabetes

### Protocol summary

**Study aim**
Evaluation and comparison of the effects of simultaneous use of chromium and vitamin D supplementation on homocysteine levels in patients with type 2 diabetes

**Design**
A randomized, double-blind, placebo-controlled clinical trial.92 patients with type 2 diabetes were randomly assigned into 4 groups, numbered 1 to 92.

**Settings and conduct**
From 92 people with type 2 diabetes up to 5 years with diabetes and using metformin medication referred to Khomein health centers and consenting to participate in drug intervention plan Taken fast blood sample. And subjects were randomly divided into four groupswith preservation routine and normal mobility and dietary habits. First, 12 hours fasting blood samples are taken before starting supplements, and serum is stored at -70 ° C for subsequent analysis. After a 16 weeks period of supplementation , 12-hour fasting blood taken again and serum will be kept at -70 ° C for subsequent analysis. After the intervention period, homocysteine levels were measured by HPLC

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Includes patients with type 2 diabetes for at least 5 years with diabetes and metformin use in the age range 25-60 years. Exclusion criteria included those with 1) insulin injection 2) inflammatory diseases 3) kidney disease 4) liver disease 5) parathyroid disease 6) pregnancy and lactation 7) anticonvulsant and steroid use 8) history of use Tobacco 9) Use of vitamins and minerals 10) Patients with hyperthyroidism and hypothyroidism.

**Intervention groups**
(I) placebo of vitamin D one tablet/ week (n=23), (II) vitamin D3 supplement at a dosage of 50000 IU/ week (n=23). (III) CrPic supplement at a dosage of 500 µg/day (n=23). (IV) both vitamin D3 at a dosage of 50000 IU/ week and CrPic at a dosage of 500 µg/day (n=23) for 16 weeks.

**Main outcome variables**
Homocysteine levels

### General information

**Reason for update**
Homocysteine assay is performed on 300 µl of additional sample of previous study with code IRCT2017052034038N1, stored at -80 C0. There is no need to re-bleeding

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190610043852N1**
Registration date: **2019-10-21, 1398/07/29**
Registration timing: **retrospective**

Last update: **2020-01-14, 1398/10/24**
Update count: **1**

**Registration date**
2019-10-21, 1398/07/29

**Registrant information**

**Name**
Fatemeh Imanparast
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 86 3417 3505
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2017-08-30, 1396/06/08

**Expected recruitment end date**
2018-01-30, 1396/11/10

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effects of the simultaneous use of chromium and vitamin D supplements on hemosysteien in type 2 diabetes

**Public title**
effects of chromium and vitamin D supplements on hemosysteien in type 2 diabetes
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with type 2 diabetes for at least 5 years. In the age range of 25-60 years 6 months before the onset of study did not change the hypoglycemic drugs and remained stable during study.
**Exclusion criteria:**
not inject insulin. Does not have severe inflammatory disease, kidney disease, liver disease, parathyroid disease, hyper and hypothyroidism didn't take any vitamin and mineral supplements 6 months prior to the study Has no history of using anticonvulsants, steroids, and tobacco in the past 6 months.
**Age**
From **25 years** old to **60 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Data analyser

**Sample size**
Target sample size: **96**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple Crash, Individual Crash Unit, Random Number Table Crash Tool.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, none of the patients not aware in the placebo group because placebo is similar to vitamin D supplement. Also the data analyzer does not know What supplement each group received. In fact, the data is given to the analyzer for analysis in 4 groups of 1 to 4.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**
not

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Arak University of Medical Sciences
**Street address**
Arak University of Medical Sciences, Basij Square, Arak
**City**
Arak
**Province**
Markazi
**Postal code**
0098-34173505
**Approval date**
2019-05-22, 1398/03/01
**Ethics committee reference number**
IR.ARAKMU.REC.1398.131

## Health conditions studied

### 1

**Description of health condition studied**
diabets
**ICD-10 code**
E08
**ICD-10 code description**
Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

**Description**
Homocysteine
**Timepoint**
before intervention, after intervention
**Method of measurement**
HPLC

## Secondary outcomes

### 1

**Description**
Weight
**Timepoint**
Before and after the interference
**Method of measurement**
scale

### 2

**Description**

Height

**Timepoint**

Before and after the interference

**Method of measurement**

metr

**3**

**Description**

blood pressure

**Timepoint**

Before and after the interference

**Method of measurement**

pressure indicator

## Intervention groups

**1**

**Description**

Intervention group: PLACEBO,CELLEROS,One pill per week, for 16 weeks months,Orally

**Category**

Placebo

**2**

**Description**

Intervention group:vitamin D, One pill per week, for 16 weeks,Orally

**Category**

Treatment - Other

**3**

**Description**

Intervention group: chromium picolinate, One pill per day, for 16 weeks, Orally

**Category**

Treatment - Other

**4**

**Description**

Intervention group four: chromium picolinate and vitamin D, One pill per day for chromium picolinate and One pill per week for vitamin D , for 16 weeks , Orally

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Fatemeh Imanparast

**Street address**

Beheshti Boulevard

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Khomein

**Province**

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Kamali

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Deputy of Research and Technology

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Fatemeh Imanparast

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**
Biochemistry
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
No more information
**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