Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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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
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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