Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of combined oral supplementation vitamin D, zinc, calcium and magnesium on glycemic control, lipid profiles, liver enzymes and CRP index in Type 2 diabetic patients

Protocol summary

Study aim

Determining the effect of combined oral supplementation vitamin D, zinc, calcium, and magnesium on glycemic control profiles, lipid profiles, liver enzymes, serum CRP in type 2 diabetic patients

Design

A controlled clinical trial, double-blind, randomized, Stratified block randomization, two groups of 39 people for involvement in two months

Settings and conduct

Patients who referred to the clinic, if they wished, completed the consent form, then received food with a 24-hour three-day recall, physical activity, and blood samples, and supplemented by a third person outside the study, and After two months, these tests will be taken

Participants/Inclusion and exclusion criteria

Entrance: Over the age of 18 and under the age of 65, people with diabetes who take the same drugs like metformin, glibenclamide, metformin-repaglantine. Exit: Pregnant and lactating people, smoking and alcohol, people with polycystic ovary syndrome, History of or suffering from heart disease and cancer, gastrointestinal diseases, history of malabsorption surgery, hormone therapy, diabetic foot ulcer and ... Consumption of any supplements up to three months before the study, changes in the medications used during the intervention , Changes in physical activity during the study

Intervention groups

The experimental group was 39 patients and the control group 39, followed by two months of intervention, in the supplementation group supplemented with 200 units of vitamin D 4 mg zinc oxide, 100 mg of magnesium oxide and 400 mg of calcium In the form of carbonate and in the placebo control group, this supplement, which is a combination, will receive sorbitol Caryon.

Main outcome variables

Zinc, insulin sensitivity, insulin resistance, fasting insulin, HbA1c, fasting glucose, lipid profile, CRP inflammatory index, liver enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190402043157N1**
Registration date: **2019-05-19, 1398/02/29**
Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**
Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

mostafa badeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3262 0640

Email address

mostafabadeli@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

2018-12-11, 1397/09/20

Actual recruitment end date
2019-02-09, 1397/11/20
Trial completion date
2019-02-09, 1397/11/20

Scientific title
The effect of combined oral supplementation vitamin D, zinc, calcium and magnesium on glycemic control, lipid profiles, liver enzymes and CRP index in Type 2 diabetic patients

Public title
The effect of simultaneous oral administration of vitamin D, zinc, calcium and magnesium on type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults (18 years of age and under 65 years of age) People with type 2 diabetes who use the same drug (metformin, glibenclamide, metformin-repaglinide).
Exclusion criteria:
Pregnant and lactating people People who are going to have a pregnancy Smoking and alcohol People with polycystic ovary syndrome (if accompanied by type 2 diabetes insulin resistance) Having any underlying heart disease and cancer Species that have kidney, liver and chronic diseases or acute inflammation (especially acute pancreatic inflammation) and thyroid gland diseases Cystic fibrosis (malabsorption) People with gastrointestinal diseases (celiac disease, Crohn's disease, peptic ulcer, diverticulosis, IBD, IBS) People undergoing gastric bypass surgery (malabsorption) People undergoing cholecystectomy (malabsorption) Specimens that were under hormone therapy Insulin injections (due to effect on body weight and insulin levels) Change in the type and dosage of the medications consumed during the intervention Not taking supplements (vitamin D and calcium, etc.) up to three months before the study were treated with drugs and weight loss supplements (such as orlistat or dietary supplements) People who use drugs that cause hyperglycaemia, such as oral or injectable corticosteroids (including prednisone, prednisolone, dexamethasone, triamcinolone, hydrocortisone or betamethasone) People with diabetic foot ulcer Change in the level of physical activity and intense physical activity
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **78**
More than 1 sample in each individual
Number of samples in each individual: **39**
Serum zinc level and biochemical parameters such as fasting blood glucose, insulin blood, Hba1c, LDL, HDL, kidney cholesterol, TG, hepatic alzymers (ALT, AST, ALP), inflammatory factor including CRP with original dialab kits Autoimmunoassay BT-1500, body composition and anthropometric (BMI, BFM, PBF, VFA, FFM) (SMM, WHR) will be done with Inbody 770 Analyzer in Nursing Research Laboratory of Urmia Medical School
Actual sample size reached: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into two groups based on the information obtained from them and stratified block randomization: the intervention group will be 39 and the control group will be 39, the intervention period will begin two months and after the preparation period.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the researchers are participants and blind analyst, and the third one is outside the study, categorized and encoded by Mclarha, and the participants first start by identifying the work involved in the work There is no information about placebo or maclaques.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia, Resalat Blvd, Emergency avenue
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2018-04-18, 1397/01/29
Ethics committee reference number
IR.UMSU.REC.1397.057

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Serum insulin serum level (µIU / ml), 5. 10 ± 1.20 in the placebo group and 7.9 ± 2.7 in the intervention group
Timepoint
Measuring blood insulin at the beginning and end of the study
Method of measurement
Insulin ELISA will be measured

Secondary outcomes

1

Description
Total Cholesterol
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

2

Description
Triglyceride
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

3

Description
HDL
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

4

Description
LDL
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

5

Description
VLDL
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

6

Description
physical activity
Timepoint
Before and after intervention
Method of measurement
questionnaire MET

7

Description
Systolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Mercury pressure gauge

8

Description
Diastolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Mercury pressure gauge

9

Description
BMI
Timepoint
Before and after intervention
Method of measurement
With the Inbody 770 Analyzer

10

Description
Body composition
Timepoint
Before and after intervention
Method of measurement
With the Inbody 770 Analyzer

11

Description
fasting blood sugar
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

12

Description
HbA1C
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

13

Description
CRP
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

14

Description
ALT
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

15

Description
AST
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

16

Description
GGT
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

17

Description
ALP
Timepoint
Before and after intervention
Method of measurement
Dialab Kit Original Ultraviolet Auto analyzer BT-1500

18

Description
HOMA-IR
Timepoint
Before and after intervention
Method of measurement
Through the formula

19

Description
QUICKI
Timepoint
Before and after intervention
Method of measurement
Through the formula

Intervention groups

1

Description
Intervention group: In this two-month course, a double-blind, double-blind, oxidized zinc oxide 100 mg magnesium oxide and 400 mg calcium carbonate in the form of pills containing 200 units of vitamin D, 4 mg of zinc oxide, Which will be provided by the pharmaceutical company Raha farma in Isfahan. This supplement will be distributed under the supervision of the Ministry of Health at the pharmacies. Diabetes patients will once again take the supplements twice daily in the afternoon and in the afternoon.
Category
Treatment - Drugs

2

Description
Control group: During this two month period, the placebo will receive this supplement, which is a combination of Sorbitol Caryon, which is being prepared by the Pharmaceutical Company Rahafarma of Isfahan. Diabetes patients will once again take place twice a day once in the morning and next in the afternoon.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mostafa Badeli
Street address
Urmia, Resalat Blvd, Emergency Avenue
City
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Postal code
5714783734
Phone
+98 44 3223 4897
Email
mostafabadeli@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Urmia, Resalat Blvd, Emergency Avenue
City
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Postal code
5714783734
Phone
+98 44 3223 4897
Email
mostafabadeli@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mostafa badeli
Position
Masters student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact
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Oroumia University of Medical Sciences
Full name of responsible person
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Position
Master student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
mostafabadeli
Position
Master student
Latest degree
Master
Other areas of specialty/work
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urmia
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The title of the document, titled Vitamin D, Calcium, Zinc and Magnesium, is shared with type 2 diabetic patients. All data is shared after the atom

When the data will become available and for how long

Starting this information is available from 1400 and will be published six months after the publication.

To whom data/document is available

Only scholars working in academic and academic institutions can access this data.

Under which criteria data/document could be used

Only these data can be used by researchers for systematic review and meta-analysis, and can only perform meta-analytic statistical tests.

From where data/document is obtainable

Urmia University of Medical Sciences, Urmia, Resalat Blvd, emergency avenue Postcode 5714783734 -04432234897

What processes are involved for a request to access data/document

First, contact the medical school to give them more information.

Comments