

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 Cation.

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 ($\mu\text{IU} / \text{ml}$), 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

Urmia

Province

West Azarbaijan

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

Urmia

Province

West Azarbaijan

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

Street address

Urmia, Resalat Blvd, Emergency Avenue

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

mostafabadeli@yahoo.com

Person responsible for scientific inquiries

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

Nutrition

Street address

Urmia, Resalat Blvd, Emergency Avenue

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

mostafabadeli@yahoo.com

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

Nutrition

Street address

Urmia, Resalat Blvd, Emergency avenue

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

mostafabadeli@yahoo.com

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