

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Study of the daily oral calcium effect on serum B12 level among patients Diabetes with type II metformin consumer

Protocol summary

Summary

Objective: Evaluation the effect of daily intake calcium on serum B12 levels in people with type II diabetes mellitus who are used metformin Study design: Random (block randomization size of 4, 8, 10), one blind side, control with placebo, single central Experimental population: All people with type II diabetes mellitus who are used metformin referred to the endocrinology clinic of Shahid Beheshti Hospital of Qom Inclusion criteria: people with type II diabetes mellitus are treated to metformin in aged 30 to 60 years; People with type II diabetes mellitus are treated to metformin for the last 2 years; diabetics are treated with 1 to 2 gram metformin. Exclusion criteria: Current intake of calcium or B12 vitamin supplements; people with malabsorption, renal failure, kidney stone, liver disease, lung disease, anemia, gastrointestinal surgery, cancer, antibiotic use in the last two weeks; people with B12 vitamin deficiency Sample size, intervention, intervention time and outcome of the study: sample size of this study is 60 persons will be divided into two groups (Intervention and Control groups). Intervention group: To each patients are given metformin with 200 pcs of calcium carbonate tablet (daily 1 gram). The serum B12 level and neuropathy will be measured after 3 months of calcium uptake. Control group: To each patients are given metformin with 200 pcs of placebo tablet. Patients will be monitored that how to use of tablets for monthly by telephone. Medicine or placebo prescribing will be perform by project secretary with encoding in a particular office without the knowledge of participants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081925732N26**

Registration date: **2017-09-04, 1396/06/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-04, 1396/06/13

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

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Email address

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the daily oral calcium effect on serum B12 level among patients Diabetes with type II metformin consumer

Public title

Study of the daily oral calcium effect on serum B12 level among patients Diabetes with type II metformin consumer

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: people with type II diabetes mellitus are treated to metformin in aged 30 to 60 years; People with type II diabetes mellitus are treated to metformin for the last 2 years; diabetics are treated with 1 to 2 gram metformin. Exclusion criteria: Current intake of calcium or B12 vitamin supplements; people with malabsorption, renal failure, kidney stone, liver disease, lung disease, anemia, gastrointestinal surgery, cancer, antibiotic use in the last two weeks; people with B12 vitamin deficiency

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, SafaShahr Blvd, Qom

City

Qom

Postal code

3516987366

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.MUQ.REC.1396.48

Health conditions studied

1

Description of health condition studied

Diabetic

ICD-10 code

N08.3*

ICD-10 code description

Diabetic nephropathy

Primary outcomes

1

Description

Vitamin B12 serum

Timepoint

Before and after intervention

Method of measurement

blood test

2

Description

Calcium

Timepoint

Before and after intervention

Method of measurement

Exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To each patients are given metformin with 200 pcs of calcium carbonate tablet (daily 1 gram). The serum B12 level and neuropathy will be measured after 3 months of calcium uptake.

Category

Treatment - Drugs

2

Description

Control group: To each patients are given metformin with 200 pcs of placebo tablet. The serum B12 level and neuropathy will be measured after 3 months of calcium uptake.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine Clinic of Shahid Beheshti Hospital in Qom

Full name of responsible person

Azam Farahani

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qom University of Medical Sciences, Deputy of
Research and Technology.

Full name of responsible person

Hossein Saghafi

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Qom University of Medical Sciences, Safashahr Blvd,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qom University of Medical Sciences, Deputy of Research
and Technology.

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**

Qom University of Medical Sciences

Full name of responsible person

Mahmoud Parham

Position

Endocrinology

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Email**Web page address****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