

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of serum levels of homocysteine, folic acid, and vitamin B12 in patients with type 2 diabetes mellitus before and after treatment with metformin

Protocol summary

Summary

This clinical trial was conducted with the aim of comparison of serum levels of homocysteine, folic acid and vitamin B12 before and after 3 months treatment with metformin. Fifty patients with type 2 diabetes mellitus who referred to endocrine clinic participated in this survey. Inclusion criteria were: age range of 30 to 75 years old; negative history of previous diabetic ketoacidosis; recent diagnosis of type 2 diabetes mellitus; fasting blood sugar 135 milligram per deciliter or more and 2 hours postprandial blood sugar 180 milligram per deciliter or more. Exclusion criteria included: not using drugs with effect on folate and vitamin B12 metabolism; pregnancy; history of surgery on gastrointestinal tract; impaired renal function; class III or more of congestive heart failure; hypothyroidism. In the beginning the patients followed diet regimen for 3 months and their blood sugar was checked at 6 weeks intervals then treatment with metformin from a minimum dose of 500 milligrams daily to maximum dose of 2500 milligrams daily, according to their blood sugar level, was started. After 3 and 6 months of starting the study their weight was measured and their blood samples were taken for measurement of homocysteine, folic acid, vitamin B 12, lipids and Glycated hemoglobin (HbA1c) levels. Also, their height was measured in the beginning for calculation of their Body Mass Index (BMI)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011614717N2**

Registration date: **2015-05-18, 1394/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-18, 1394/02/28

Registrant information

Name

Fariba Karimi

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 71 3624 6096

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karimif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-12-06, 1390/09/15

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serum levels of homocysteine, folic acid, and vitamin B12 in patients with type 2 diabetes mellitus before and after treatment with metformin

Public title

Assessment of the effect of metformin on serum levels of homocysteine, folic acid, and vitamin B12 in patients

with type 2 diabetes mellitus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age range of 30 to 75 years old; type 2 of diabetes mellitus; absent previous history of diabetic ketoacidosis; fasting blood sugar 135 milligrams per deciliter or more and 2 hours postprandial blood sugar 180 milligrams per deciliter or more. Exclusion criteria: consumption of vitamin B12, folic acid or drugs with effects on folate metabolism (such as: anticonvulsants, antirheumatologic, and antineoplastic medications); renal function defect (serum creatinine level greater than 1.3 milligram in deciliter) ; pregnancy or trying to become pregnant; history of surgery on gastrointestinal tract (stomach or ileum) ; history of hypothyroidism; class III or more of congestive heart failure presence of malignant disorders; presence of psychiatric diseases; treatment with antibiotics; uncontrolled blood sugar during the intervention

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

not registered yet

Secondary trial Id

not registered yet

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City

Shiraz

Postal code

7134814336

Approval date

2011-11-05, 1390/08/14

Ethics committee reference number

90/325855

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 2

ICD-10 code

E11

ICD-10 code description

Non insulin dependent diabetes mellitus

Primary outcomes

1

Description

Serum level of homocysteine

Timepoint

In the beginning and 3 to 6 months after starting the intervention

Method of measurement

Measurement of serum level of homocysteine by enzyme immunoassay method

2

Description

Serum level of folic acid

Timepoint

In the beginning and 3 to 6 months after starting the intervention

Method of measurement

Measurement of serum level of folic acid by radioimmunoassay method

3

Description

Serum level of vitamin B12

Timepoint

In the beginning and 3 to 6 months after starting the intervention

Method of measurement

Measurement of serum level of vitamin B12 by radioimmunoassay method

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

In the beginning and then every 6 weeks

Method of measurement

Blood test by glucose dehydrogenase method

2

Description

Two hours postprandial blood sugar

Timepoint

In the beginning and then every 6 weeks

Method of measurement

Blood test by glucose dehydrogenase method

3

Description

Lipid profile

Timepoint

In the beginning and then 3 and 6 months after starting the study

Method of measurement

Blood test by cholesterol oxidase/ peroxidase and glycerol phosphate oxidase/ peroxidase and direct enzymatic methods

4

Description

Glycated hemoglobin (HbA1c) level

Timepoint

In the beginning and 3 to 6 months after starting the study

Method of measurement

Direct enzymatic assay

5

Description

Weight of the patients

Timepoint

In the beginning and 3 and 6 months after starting the study

Method of measurement

By standard stadiometer

6

Description

Body mass index

Timepoint

In the beginning and 3 and 6 months after starting the study

Method of measurement

By the formula: weight in kilograms divided by height in meters squared

Intervention groups

1

Description

In the beginning patients followed diet regimen alone for three months

Category

Treatment - Drugs

2

Description

After 3 months of diet regimen alone, treatment with metformin with a minimum dose of 500 milligrams daily to a maximum dose of 2500 milligrams per day in three divided doses by mouth, according to their blood sugar, was started. In this study 500 milligrams tablets of metformin which manufactured by Osveh company were used

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Motahari Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Doctor Fariba Karimi

Street address

Shaheed Motahari Clinic, Namazee Square, Zand Street, Shiraz, Iran

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2

Recruitment center

Name of recruitment center

Shaheed Faghihi Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Doctor Fariba Karimi

Street address

Iran, Shiraz, Zand Street, Shaheed Faghihi Hospital, Shaheed Faghihi Clinic, Clinic of Internal Medicine, Second Floor

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

Doctor Basyr Hashemi

Street address

Department of Vice-Chancellor for Research of Shiraz University of Medical Sciences, 7th Floor, Central

Building of Shiraz University of Medical Sciences,
Zand Street, Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

CT-87-4021

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

Yes

Title of funding source

Vice-Chancellor for Research of Shiraz University of
Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Fariba Karimi

Position

Internist with subspecialty in Endocrinology and
Metabolism, Assistant professor of Shiraz Universit

Other areas of specialty/work

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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