Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Folic acid supplementation on biochemical and Redox indices in patients with type 2 diabetes

Protocol summary

Summary

To determine the effect of Folic acid supplementation on biochemical and Redox indices in patients with type 2 diabetes, seventy men with type2 diabetes who met the inclusion criteria were included in the study. These patients were recruited from Imam Reza endocrine clinic of Tabriz University of Medical Sciences, Iran. The patients were randomly assigned, in a double blind fashion, to receive placebo or folic acid (5mg/day) for 8weeks, sequentially. Weight, height and blood pressure were measured at the first and the end of study. Fasting venous blood samples were taken before and after treatment for biochemistry and Redox indices, including: fasting blood sugar, lipid profiles, HbA1C, insulin, serum vitamin B12, folic acid, hemocysteine, Serum malondialdehyde (MDA), Total antioxidant capacity (TAC). HOMA-IR are calculated by following formula: fasting insulin (mu/ml)* fasting glucose (mg/dl)/405. Also 3-day food intake 24h recalls were taken from all subjects, at first and during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811033140N1**
Registration date: **2010-03-31, 1389/01/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-03-31, 1389/01/11

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences and Nutrition research committee

Expected recruitment start date

2009-10-18, 1388/07/26

Expected recruitment end date

2010-03-16, 1388/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Folic acid supplementation on biochemical and Redox indices in patients with type 2 diabetes

Public title

The effect of Folic acid supplementation in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: -having the type 2 diabetes -voluntary consent for participation in the study -use of metformin at least 1500mg/day for >6month. Exclusion criteria: -use of multivitamin-mineral supplements at least 6month before the study -smoking, alcohol abuse -treatment with insulin -having the hepatic, renal failure, cardiovascular,

celiac, gastrointestinal, rheumatic, endocrine, thyroid disorders -leukemia -abnormalities in the enzymes that metabolize the hemocysteine –use of corticosteroids, anticonvulsants, isoniazid

Age
From **36 years** old to **78 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Golbad street

City
Tabriz

Postal code

Approval date
1388-09-05, 769/01/-560

Ethics committee reference number
5/4/6827

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
non-Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Improvement of antioxidant indices

Timepoint
8weeks

Method of measurement
Assessments of changes in MDA and TAC

2

Description
FBS, insulin resistance, HbA1C, creatinine, lipid profiles

Timepoint
8weeks

Method of measurement
laboratory

3

Description
Serum hemocysteine, folic acid and B12

Timepoint
8weeks

Method of measurement
laboratory

Secondary outcomes

1

Description
Blood pressure

Timepoint
8weeks after the supplementation

Method of measurement
Sphygmometer

2

Description
Body Mass Index

Timepoint
8 weeks after the supplementation

Method of measurement
Weight(Kg)/height(m2)

Intervention groups

1

Description
Control group: plasebo

Category
Placebo

2

Description
Interventinal group: 5mg/day of oral folic acid

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza endocrine clinic
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz university of medical sciences & Nutrition research committee
Full name of responsible person
Bahram Pourghassem
Street address
Health & Nutrition Faculty
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz university of medical sciences & Nutrition research committee
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
Health and Nutrition Faculty, Tabriz university of medical sciences
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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