

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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, homocysteine, Serum malondialdehyde (MDA), Total antioxidant capacity (TAC). HOMA-IR are calculated by following formula: $\text{fasting insulin (}\mu\text{g/ml)} \times \text{fasting glucose (mg/dl)} / 405$. 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

Intervental 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

Full name of responsible person

Bahram Pourghassem

Position

PhD

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