

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1435 7580

##### Email address

pourghassemb@tbzmed.ac.ir

##### 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(m<sup>2</sup>)

## 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**

**Street address**

Health and Nutrition Faculty of Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7580

**Fax**

**Email**

pourghassemb@tbzmed.ac.ir &

bahrampg@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz university of medical sciences

**Full name of responsible person**

Bahram Pourghassem

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Health and Nutrition Faculty of Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7580

**Fax**

**Email**

pourghassemb@tbzmed.ac.ir &

bahrampg@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Health and Nutrition Faculty

**Full name of responsible person**

Vahide Aghamohammadi

**Position**

MS

**Other areas of specialty/work**

**Street address**

Health and Nutrition Faculty of Tabriz

**City**

Tabriz

**Postal code**

**Phone**

**Fax**

**Email**

v\_agamohammadi@yahoo.com

**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*