

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A randomized clinical trial to evaluate the effect of folic acid supplementation on TID score in myocardial perfusion scan of diabetic patients.

Protocol summary

Summary

1-Major objectives : Evaluation of therapeutic effect of folic acid on transient ischemic dilatation of diabetic patients with myocardial perfusion scan. 2-Design: Randomized double blinded clinical trial. 3-Setting and conduct: This is a randomized double blinded clinical trial to evaluate the effect of folic acid supplementation on TID score in myocardial perfusion scan of diabetic patients. The endocrinologist refers 40 diabetic patients which are randomly divided into two groups, one control and one case groups. Myocardial perfusion scan is then performed for all of these patients using Dipiridamole as stress agent, a sample blood is also taken from each patient on the day of MPI to assess blood Hemocysteine level , then the case group receives capsules containing 5mg of folic acid and the control group receives placebo capsules . Each patient uses one capsule a day for two months. After two months MPI and blood sampling is performed for each patient the same way as before ,TID and blood hemocysteine level of the first time are then compared with the second time. 4-Participants: Inclusion: Type II diabetic patients Exclusion: History of anti angina treatment or revascularization. Evidence of Q wave in ECG referring to previous MI ECG based ST changes due to ischemia Active asthma Type II cardiac block or more. 5-Intervention: Allocation of folic acid or placebo randomly to the patients. 6-Main outcome measures : Changes in TID level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120111624N1**
Registration date: **2013-01-02, 1391/10/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-02, 1391/10/13

Registrant information

Name

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tehran University of
Medical Sciences

Expected recruitment start date

2012-10-02, 1391/07/11

Expected recruitment end date

2013-10-02, 1392/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial to evaluate the effect of folic acid supplementation on TID score in myocardial perfusion scan of diabetic patients.

Public title

Effect of folic acid on myocardial perfusion scan

Purpose

Treatment

Inclusion/Exclusion criteria

Major Inclusion criteria: Type II diabetic patients; Major exclusion criteria: History of anti angina treatment or revascularization; Evidence of Q wave in ECG referring to previous MI; ECG based ST changes due to ischemia; Active asthma; Type II cardiac block or more;

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods str.Keshavarz boulevard,

City

Tehran

Postal code**Approval date**

2012-10-03, 1391/07/12

Ethics committee reference number

91/130/1517/3

Health conditions studied**1****Description of health condition studied**

Coronary artery disease (Atherosclerosis)

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes**1****Description**

Myocardial perfusion

Timepoint

Before and two months after intervention

Method of measurement

MPI

Secondary outcomes**1****Description**

TID

Timepoint

After MPI

Method of measurement

QPS software

2**Description**

Hemocysteine blood level

Timepoint

Before MPI

Method of measurement

Blood level of homocysteine

Intervention groups**1****Description**

The intervention group receives 5mg folic acid (powdered) in capsules . 5mg folic acid (1 capsule) daily for 2 months.

Category

Treatment - Drugs

2**Description**

The control group receives placebo also powdered in capsules. 1 capsule daily for 2 months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Research institute for nuclear medicine,Tehran

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Akbar Fotouhi

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Keshavarz boulevard, Vice chancellor for Research,
Tehran University of Medical Sciences

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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

Vice chancellor for Research, Tehran 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

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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