

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of effect of folic acid in Buerger`s disease on homo cysteine and clinical status

Protocol summary

Summary

This is an experimental placebo controlled double blinded study. Study group is 30 identified patients who are randomly allocated in drug or placebo group. All of the patients are advised stop smoking and receive standard routine therapy of Buerger`s disease. Inclusion criteria contains: Buerger`s patients referring to Alzahra hospital who have consent of participation to study. No history of hypertension, diabetes mellitus, ischemic heart disease, cerebrovascular disease or collagen vascular disease. Exclusion criteria are: surgical (sympathectomy or vascular bypass) or medical (Illeoprost or corticosteroid) changes in treatment, or starting Aspirin, calcium channel blocker, VitB6 or VitB12 or stop smoking during the study. At the start of the study demographic data, Wagner wound scale, Visual Analog Scale (VAS) of pain, Allen test, healing scale, wound size and major and minor amputation, homocysteine, anticardiolipin and number of steps walking without pain is recorded. Intervention is was one tablet containing 5 mg Folic acid and placebo (the same as color, size, and weight). The patients will be evaluate at the first , 2nd and 6th month for Homocysteine, Anticardiolipin, scale of wound, scale of pain, size of wound, major and minor amputation, sense of patient about healing and the number of steps the patient can walk without pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108012106N2**

Registration date: **2011-08-04, 1390/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-04, 1390/05/13

Registrant information

Name

Afroz Eshaghian

Name of organization / entity

Isfahan university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Applied Physiology Research center, Isfahan University of Medical Science

Expected recruitment start date

2004-01-01, 1382/10/11

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of folic acid in Buerger`s disease on homo cysteine and clinical status

Public title

Effect of folic acid in Buerger`s disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Buerger`s patients referring to Alzahra hospital who have consent of participation to study;

history of smoking; onset of disease before 50 year-old; upper limb involvement or phlebitis migrans; obliterative arterial disease below popliteal artery and no risk factor of atherosclerosis except smoking; no history of hypertension, diabetes mellitus, ischemic heart disease, cerebrovascular disease or collagen vascular disease. Exclusion criteria: surgical (sympathectomy or vascular bypass) or medical (Illeoprost or corticosteroid) changes in treatment; starting Aspirin, calcium channel blocker, VitB6 or VitB12 or stop smoking during the study; drug incompliance during the study and not willing to continue the study.

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 30

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**

Isfahan University of Medical Sciences Ethics Committee

Street address

Isfahan University of medical sciences, Hezar Jarib St

City

Isfahan

Postal code**Approval date**

2004-01-01, 1382/10/11

Ethics committee reference number

2436

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

Buerger`s disease

ICD-10 code

I73.1

ICD-10 code description

Thromboangiitis obliterans [Buerger]

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

Scale of wound

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Wagner Scale

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

Homocysteine

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Lab test

2**Description**

Scale of pain

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

VAS

3**Description**

Anticardiolipin

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Lab test

4**Description**

Size of wound

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Millimeter

5**Description**

Number of steps walking without pain

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Number

6

Description

Sense of patient about healing

Timepoint

At the 2nd and 6th months

Method of measurement

Ask a patient

7

Description

Minor amputation

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Number

8

Description

Major amputation

Timepoint

At the beginning and 2nd and 6th months

Method of measurement

Number

Intervention groups

1

Description

Intervention group will take tab. Folic acid 5 mg per day, for 6 month

Category

Treatment - Drugs

2

Description

Control group will take placebo(the same color, size, box to tab Folic acid 5 mg) one tablet per day for 6 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Applied Physiology Research Center

Full name of responsible person

Sedighe Asgari

Street address

Sofo St, Applied Physiology research center

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Applied Physiology Research Center

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

Applied Physiology Research Center

Full name of responsible person

Afroz Eshaghian

Position

Resident of Otolaryngology

Other areas of specialty/work

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Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Ali Akbar Beigi

Position

Assolciated professor of vascular surgery

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Applied Physiology Research center

Full name of responsible person

Afrooz Eshaghian

Position

Resident of Otolaryngolgy

Other areas of specialty/work**Street address**

Sofe st., Al-Zahra hospital

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