Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison the Effect of Aspirin and Warfarin in Prevention of Recurrence of Ischemic Stroke in Patients With High Risk Patent Foramen Ovale

Protocol summary

Summary

The purpose of this study is to compare the effect of Aspirin and Warfarin in preventing the recurrence of ischemic stroke in patients who have high risk patent foramen ovale (PFO); according to contrast-trans cranial doppler sonography findings. High risk PFO is defined as: 1. Accompany with atrial septal aneurysm 2. More than 50 bubbles observe during contrast-echocardiography 3. Multiple territory infarcts 4. Infarction following valsalva maneuver. All patients with ischemic stroke and PFO with above criteria will be included in this study. It was predicted that 35 patients will be recruited. Patients undergo contrast Trans-cranial doppler sonography and number of Micro-Embolic Signals (MES) will be counted. Then subjects will be divided in two groups blindly to receive Warfarin or Aspirin. They will be followed for 12 months for recurrence of stroke or complication of the managements. At the end of the study the preventive effect of Warfarin and Aspirin would be compared.

General information

Acronym

AWHPFO

IRCT registration information

IRCT registration number: **IRCT138805192323N1**
Registration date: **2009-11-21, 1388/08/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-11-21, 1388/08/30

Registrant information

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2008-10-31, 1387/08/10

Expected recruitment end date

2010-07-22, 1389/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Aspirin and Warfarin in Prevention of Recurrence of Ischemic Stroke in Patients With High Risk Patent Foramen Ovale

Public title

Treatment of High Risk Patent Foramen Ovale According to Contrast-trans Cranial Doppler Sonography

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: permanent or transient cerebral or retinal ischemia, age more than 18 years old, more than 50 bubbles in echocardiography, presence of atrial septal aneurysm, multiple infarctions in brain CT Exclusion

criteria: more than 50% stenosis in colour doppler sonography of neck arteries, thrombosis or ulcerated plaques in neck arteries, other cardiac definite source of stroke

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mohamad Hossein Dabaghmanesh

Street address
Main University building, division of research

City
Shiraz

Postal code

Approval date
2009-10-07, 1388/07/15

Ethics committee reference number
CT-88-4639

Health conditions studied

1

Description of health condition studied
permanent or transient cerebral or retinal ischemic attack

ICD-10 code
G45-G46

ICD-10 code description
Transient Cerebral Ischaemic attacks and related syndromes-Vascular syndromes of Brain in Cerebrovascular Diseases

Primary outcomes

1

Description
permanent or transient cerebral or retinal ischemic attack or death due to any cause

Timepoint
3 months, 6 months, 9 months and 12 months after intervention

Method of measurement
by phone for recurrence of stroke

Secondary outcomes

empty

Intervention groups

1

Description
Aspirin 80 mg TID orally and continuing for 1 year until progression or unacceptable toxicity develops.

Category
Treatment - Drugs

2

Description
Warfarin 5 mg per day orally and adjust it to achieve INR between 2 and 3 and continue it for 1 year until progression or unacceptable toxicity develops

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Reza Nemati

Street address
Namazi hospital, Zand square.

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Abdolhamid Shariat

Street address
Zand street, Main University Building, division of research

City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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Person responsible for updating data

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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