

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison between the efficacy of Plavix and Clopidex in Post stroke patients with Ischemic heart disease

Protocol summary

Summary

The aim of this study is to evaluate the efficacy of Plavix versus Clopidex in Post stroke patients with Ischemic heart disease. After definite diagnosis of both diseases (ischemic stroke & coronary heart disease) and qualifying for inclusion in this study, the patients were randomly placed in two groups. Patients with contraindications of using anticoagulants will be excluded. finally two groups of 60 cases will be included. The first group will be given Clopidex tablets made in Exir Pharmaceutical Company and the second group will be given foreign made Palvix (75mg/d) for one month. Clinical and demographic characteristics assessment, biochemical blood tests (Complete Blood Count, Fasting Blood Sugar, Cholesterol, Triglyceride) and aggregometry tests will be done before and after treatment. [Inclusion criteria]: Patients with Ischemic Heart Disease or ischemia; Patients consent for taking part in study; Patient cooperation in experiment pursuit and taking drugs; Patients shouldn't be participating in any other clinical trial; Not having any drug taking record in the last month. [Exclusion criteria]: Existence of any hemorrhagic diseases, for instance peptic ulcer and inner-cranial hemorrhage; Existence of accompanied diseases interfering with drugs taken; Any record of allergy to Palvix or Clopidex; Any contraindications for taking Palvix or Clopidex. (Thrombocytopenia, liver disorders, Neutropenia-...); Those of patients who needed some mechanical hemodynamic support like using balloon pump; age more than 85 years and under 18 years.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011025073N1**

Registration date: **2012-12-23, 1391/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Majid Shohrati

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

shohrati@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, Mollasadra St, Vanak Sq, Tehran, Iran.

Expected recruitment start date

2012-08-01, 1391/05/11

Expected recruitment end date

2013-08-01, 1392/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of Plavix and Clopidex in Post stroke patients with Ischemic heart disease

Public title

The efficacy of Palvix and Clopidex in Post-Stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

[Inclusion criteria]: Patients with Ischemic Heart Disease or ischemia; Patients consent for taking part in study; Patient cooperation in experiment pursuit and taking drugs; Patients shouldn't be participating in any other clinical trial; Not having any drug taking record in the last month, [Exclusion criteria]: Existence of any hemorrhagic diseases, for instance peptic ulcer and inner-cranial hemorrhage; Existence of accompanied diseases interfering with drugs taken; Any record of allergy to Palvix or Clopidex; Any contraindications for taking Palvix or Clopidex. (Thrombocytopenia, liver disorders, Neutropenia-...); Those of patients who needed some mechanical hemodynamic support like using balloon pump; age more than 85 years and under 18 years.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences, Tehran

Street address

Mollasadra St, Vanak Sq,

City

Tehran

Postal code

Approval date

2011-02-19, 1389/11/30

Ethics committee reference number

340/2/5347/س

Health conditions studied

1

Description of health condition studied

ischemic cerebrovascular stroke

ICD-10 code

I63.4

ICD-10 code description

Cerebral infarction due to embolism of cerebral arteries

Primary outcomes

1

Description

coagulation profile

Timepoint

baseline and one month later

Method of measurement

using platelet count, bleeding time and coagulation time

Secondary outcomes

1

Description

platelet aggregation

Timepoint

baseline and one month later

Method of measurement

aggrigometry test

Intervention groups

1

Description

Tablet Iranian Clopidogrol made by Exir Co. 75 mg daily for 1 month as the case group, one per day

Category

Treatment - Drugs

2

Description

Tablet Plavix (75 mg) per os (orally) daily were used for control group for one month, one per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatall University Hospital

Full name of responsible person

Dr Majid Shohrati, Dr Maryam Moshkani

Street address

Mollasadra st, Vanak Sq,
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr Majid Shohrati
Street address
Mollasadra st, Vanak sq
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baqiyatallah 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
Baqiyatallah University of Medical Sciences, Chemical Injuries Research Center

Full name of responsible person

Dr Majid Shohrati

Position

Associate professor

Other areas of specialty/work

Street address

Mollasadra st, Vanak sq

City

Tehran

Postal code

Phone

+98 21 8860 0067

Fax

Email

shohratimajid@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr Majid Shohrati

Position

Associate Professor

Other areas of specialty/work

Street address

Mollasadra st, Vavak Sq

City

Tehran

Postal code

Phone

+98 21 8860 0067

Fax

Email

shohratimajid@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences, Tehran, Iran.

Full name of responsible person

Dr Majid Shohrati

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+98 21 8860 0067

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shohratimajid@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