

# 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  
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+98 21 8860 0067  
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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**  
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Associate Professor  
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**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**  
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**Position**  
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**Other areas of specialty/work**  
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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*