Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

A comparison of the effectiveness, side effects and acceptability of Plavix and Osivix as anti platelet tablets in patients undergoing Coronary artery by pass.

Protocol summary

Summary

Anticoagulant effect of clopidogrel is utmost importance in coronary artery disease, especially in prevention of coronary stent thrombosis. Recently, a new local brand of clopidogrel has been launched, as Osvix® (by OSVEH Company, Tehran, Iran). This researchi s conducted by the aim in order to compare two locally prepared clopidogrel brands (Osvix® & Plavix®), in terms of the effect on inhibition of platelet aggregation in patients with coronary artery disease. This is a double blind randomized study. Sample population consisting of 80 patients, is admitted at Ekbatan Hospital (Hamadan, Iran) for the management of coronary artery disease. Platelet aggregation tests of all these patients will measure (by Iran Blood transfusion organization) by factors of PRP, ADP and placket count. Patients received Plavix® and Osvix® treatments regimens for one month periodically after by-pass coronary surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112178428N1**
Registration date: **2014-04-19, 1393/01/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name

Behzad Imani

Name of organization / entity

Science Hamadan University of Medical

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2012-02-05, 1390/11/16

Expected recruitment end date

2013-08-04, 1392/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effectiveness, side effects and acceptability of Plavix and Osivix as anti platelet tablets in patients undergoing Coronary artery by pass.

Public title

A comparison of the efficacy of Plavix and Osivix in patients undergoing Coronary artery by pass

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients undergoing open heart surgery Exclusion criteria: 1- Patients with a prior events of acute coronary syndrome, 2- Hepatic insufficiency, 3- History of significant bleeding disorder,4- Those already taking anti-platelet and/or anticoagulant therapy, 5- Age less than 20 and over than 75.

Age
From **20 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamadan University of Medical Sciences
Street address
Reseach Deputy, Hamadan University of Medical Scinces, Hamadan, Iran.
City
Hamadan
Postal code
6518133265
Approval date
2012-12-17, 1391/09/27
Ethics committee reference number
3214 /9 /35 /16

Health conditions studied

1

Description of health condition studied
Heart disease
ICD-10 code
I97.1
ICD-10 code description
Other functional disturbances following cardiac surgery

Primary outcomes

1

Description
Platelet-rich plasma
Timepoint
30 days after heart surgery
Method of measurement
Aggregometry

Secondary outcomes

1

Description
Adenosine diphosphate
Timepoint
30 days after heart surgery
Method of measurement
Aggrigometry

Intervention groups

1

Description
at this clinical trial study, the control group consists of 40 patients recieve Plavix tablets as an antiplatetlet agent. The prescribed dose is 75 mg of Clopidogrel per day for each group. It should be noted that all patients receive 100 mg aspirin tablet daily. In order to implementation of Ex-vivo analysis, blood is mixed with 3.8% citrate and platelet aggregometry is conducted. The amount of Adenosine diphosphate, platelet-rich plasma and platelet count is measured as indicating factors of aggrigation.
Category
Treatment - Drugs

2

Description
at this clinical trial study, the intervantion group consists of 40 patients recieve Osvix tablets as an antiplatetlet agent. The prescribed dose is 75 mg of Clopidogrel per day for each group. It should be noted that all patients receive 100 mg aspirin tablet daily. In order to implementation of Ex-vivo analysis, blood is mixed with 3.8% citrate and platelet aggregometry is conducted. The amount of Adenosine diphosphate, platelet-rich plasma and platelet count is measured as indicating factors of aggrigation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ekbatan Hospital, Hamadan,Iran.
Full name of responsible person
Behzad Imani
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Operating-room Departemnt, Hamadan University of Medical Sciences, Mahdieh St., Hamadan, Iran.

City
Hamadan

Sponsors / Funding sources

1

Sponsor
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Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Hamadan 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

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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