

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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 research is 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

Country

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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 antiplatelet 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

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Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Hospital, Hamadan,Iran.

Full name of responsible person

Behzad Imani

Street address

Operating-room Departemnt, Hamadan University of
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy of Hamadan University of Medical Sciences

Full name of responsible person
Behzad Imani

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Operating-room Departemnt, Hamadan University of Medical Sciences, Mahdieh St., Hamadan, Iran.

City
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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

Contact

Name of organization / entity
Hamadan University of Medical Sciences

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Behzad Imani

Position
Faculty member, Master of Sciences in Nursing

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