Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Osvix versus Plavix in cardiovascular event after coronary stenting

Protocol summary

Summary

This study is designed to evaluate the clinical effect of Osvix versus Plavix in preventing cardiovascular events after coronary stenting, so if Osvix shows the positive effect, we can replace Plavix with Osvix. Our sample size was 450 and the study duration was approximately 2 years. Our studied population is patients who are referred to hospital for coronary stenting. Patients were divided into two groups: 1. bare metal stent (BMS) 2. Drug eluting stent (DES) and each of these groups were divided into two groups: receiving Osvix or Plavix double-blindly. After evaluating inclusion and exclusion criteria, all the information are entered in special forms. Patients with bare metal stent were treated by study drug for 1 month and patients with drug eluting stent are treated by study drug for 6 months. All patients after hospital discharge were followed for 6 months in BMS and 1 year in DES by phone, regularly. Patients with BMS were visited at the end of first month and DES at the end of first and sixth month. During this period, we evaluated cardiovascular events (like in-stent thrombosis, myocardial infarction, stroke …)

General information

Acronym
OPCES

IRCT registration information
IRCT registration number: **IRCT138712111723N1**
Registration date: **2009-06-20, 1388/03/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2009-06-20, 1388/03/30

Registrant information

Name
Alireza Khosravi

Name of organization / entity
Isfahan Cardiovascular Research Center

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Osve Pharmacological Institution

Expected recruitment start date
2007-03-10, 1385/12/19

Expected recruitment end date
2009-03-19, 1387/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Osvix versus Plavix in cardiovascular event after coronary stenting

Public title
Osvix versus Plavix in cardiovascular event after coronary stenting

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Stents with diameter ≥2.5 mm approved by ministry of health in Iran, no evidence of significant thrombus in Angiography before stenting, presence of necessary cooperation for follow up
Exclusion criteria: Previously taken Plavix, Ticlopidin, Warfarin or Osvix for other reasons, Co-morbid diseases with predicted survival less than 6 months, primary PCI for ST elevation MI, LVEF< 30%, Stent in vein grafts or

LIMA, patients that need GP IIb IIIa blocker before or after stenting, history of allergy to Plavix or Osvix, any contraindication to Plavix or Osvix (liver dysfunction, thrombocytopenia, notropenia), complete vessel occlusion without clinical symptom of viability (infarct vessel), cardiogenic shock, need to mechanical hemodynamic support like Intra-aortic balloon pump using rotablator, thrombectomy, using vascular brachytherapy or DCA during procedure, Stenting of unprotected left main coronary artery, prior enrolment in OPCES trial In following patients, study drug must be stopped and unblended drug will Prescribe for them. a. Patients with early post PCI angina with evidence of ischemia or infarction at ECG or lab exam b. undergoing target vessel revascularization (CABG, PCI) c. Residual dissection after PCI or coronary artery perforation d. Thrombosis in vessel after stenting

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **450**
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

1

Registry name
Secondary trial Id
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan Cardiovascular Research Center
Street address
Sedighe tahere Cardiovascular Research Center-khoram ave. Darvaze Tehran-Isfahan
City
Isfahan
Postal code
81465-1148
Approval date
empty
Ethics committee reference number
462/پ

Health conditions studied

1

Description of health condition studied
cardiovascular event after coronary stenting
ICD-10 code
I20-I21-I2
ICD-10 code description
Angina pectoris - Acute myocardial infarction - Other acute ischaemic heart diseases

Primary outcomes

1

Description
Incidence of cardiovascular event
Timepoint
Every day during the first week, then every week for 6 months or 1 year
Method of measurement
phone follow up or visit

Secondary outcomes

1

Description
hematological or dermatological complication
Timepoint
Every day during the first week and every week for 6 months or 1 year
Method of measurement
visit and labratoary tests

Intervention groups

1

Description
Osvix 6 tablets before PCI, continue with 1 tablet daily after PCI For 1 month in Bare metal stent
Category
Treatment - Drugs

2

Description
Plavix 6 tablets before PCI, continue with 1 tablet daily after PCI For 1 month in Bare metal stent
Category
Treatment - Drugs

3

Description
Osvix 6 tablets before PCI, continue with 1 tablet daily after PCI For 1 month in Bare metal stent
Category
Treatment - Drugs

4

Description
Plavix 6 tablets before PCI, continue with 1 tablet daily after PCI For 6 months in Drug eluting stent
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran hospital
Full name of responsible person
Dr. Alireza Khosravi
Street address
Sedighe Tahere Cardiovascular Research center, Khoram St
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2

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr.Alireza Khosravi
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Cardiovascular Research Center, Khoram st., Darvazeh Tehran
City
Isfahan

3

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Samad Ghafari
Street address
City
Tabriz

4

Recruitment center
Name of recruitment center
Ali Asghar Hospital
Full name of responsible person
Dr. Mohamad Ali Ostovan
Street address
Ali asghar Hospital, Meshkinfam St
City
Shiraz

5

Recruitment center
Name of recruitment center
Madani Hospital
Full name of responsible person
Dr. Mehrdad Namdari
Street address
Madani hospital, Emam hosein St
City
Khoram Abad

6

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Mehdi Hassan Zadeh
Street address
Ghaem hospital, Ahmad Abad St.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Osve Pharmacology Institute
Full name of responsible person
Dr. Kebriai Zadeh
Street address
Floor 3, No2, Golbarg 4 Ave., Fakhar moghadam, Dadman Blvd, Shahrak Gharb, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Osve Pharmacology Institute
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
Cardiovascular Research Center, Isfahan University of Medical Sciences

Full name of responsible person
Dr. Alireza Khosravi

Position
Cardiologist, Assistant Professor

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